HTA
Human Tissue Authority

Guidance for Transplant Teams and Independent Assessors

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Contents

Guidance for Transplant Teams and Independent Assessors

1. This document provides guidance to Independent Assessors (IAs), clinicians and transplant teams about the regulatory requirements for the assessment of prospective living organ donations by the Human Tissue Authority (HTA). For the purpose of this guidance document, 'organ' refers to a kidney; or a liver or lung lobe, from living donors. In addition, where this document refers to adults who lack capacity, this also includes children who do not have competency.

2. This guidance, along with 'The Quality and Safety of Organs Intended for Transplantation: a Documentary Framework', supplements the HTA's code of practice F: Donation of solid organs and tissue for transplantation.

The Legislative Framework

The Human Tissue Act 2004

3. 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.

4. 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.

5. Under section 33 of the HT Act, a commitable offence occurs when someone removes or uses 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 lifted (see paragraphs 8 to 10).

6. Scottish law covering living organ donation is similar to the law in the rest of the UK, although there are some significant differences (see paragraphs 11 to 14).

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

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

8. The Regulations is the secondary legislation that sets out legal requirements that must be met in order for the HTA to give approval for living organ donations.

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

   - that no reward has been given or is to be given; and
   - the removal of transplantable material requires consent for its removal, provided that it is fit for the purpose of transplantation, or its removal for that purpose is otherwise lawful.

10. This document describes the way in which the HTA applies the HT Act and the Regulations.

The Scottish Legal Framework

11. The HTA assesses all living organ donation cases on behalf of the Scottish Government.

12. The legal framework for living donation and transplantation is set out in section 17 of the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), supplemented by the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (referred to in this document as the Regulations (Scotland)).

13. The Regulations (Scotland) refer to decisions for 'the Scottish Ministers'. Scottish Ministers have agreed that the HTA will act on their behalf in relation to cases of living donation in Scotland, in order to promote consistency of approach across the UK. As a result, there is no distinction in the Regulations (Scotland) about decisions which can be delegated to an executive team, and those which have to be taken by a panel of no fewer than three Authority Members of the HTA. In practical terms, however, that distinction will be

applied to Scottish cases in the same way as it is applied to equivalent cases in the rest of the UK.

14. Further and more detailed information on the HTA's role in assessing living donation cases in Scotland, can be found in the 'Human Tissue Authority Guidance for transplant teams, Independent Assessors and Accredited Assessors in Scotland'.

The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (SI 2012 no.1501) (Quality and Safety (organs) regulations) and Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014

15. The HTA is also the body that licences establishments to ensure the quality and safety of organs intended for transplantation across England, Wales, Northern Ireland and Scotland. The HTA is the Competent Authority in the UK.

16. The HTA has published the Quality and Safety of Organs Intended for Transplantation: a documentary framework, and this should be referred and consulted to for information and guidance on licensing requirements.

Other legislation

17. The HTA must consider other legislation when carrying out its duties, such as: The Mental Capacity Act (MCA) 2005, the Adults with Incapacity (Scotland) Act 2000, the Mental Capacity Act (Northern Ireland) 2016 and the Human Rights Act (HRA) 1998, which have a bearing on the way the HTA conducts its role. In addition, the HTA must act in accordance with public law principles. These oblige the HTA to act within its lawful powers; to act reasonably and to follow fair procedures.

18. By law, the HTA has a role in ensuring that individuals should only make donations if they have capacity (in the case of adults) or competency (in the case of children), whilst making sure that an informed and voluntary decision has been made, free from duress and coercion. The HTA must also guarantee that individuals receive appropriate medical advice and understand that there is no reward for organs. The HTA recognises that this role must be balanced with the rights of the individual, set out in other legislation. Specifically, that a person should be assumed to have capacity to

consent (under the MCA, Mental Capacity Act (Northern Ireland) 2016 and Adults with Incapacity (Scotland) Act 2000) and that every person with capacity has an almost absolute right to sovereignty over their own body, as a result of the incorporation of article 8 of the European Convention on Human Rights under the HRA.

The Human Tissue Authority

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

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

Overview of the regulatory framework for living organ donation

21. The purpose of regulating living donation in the UK is to make sure that donors are not forced to act against their wishes, and to safeguard against people trafficking for the purpose of organ donation. In this way, regulation acts as a deterrent to these practises, so that they do not adversely affect or influence individual cases.

22. The regulatory requirements for living donor transplantation are set out in the HT Act and the Regulations.

23. The HTA's role is to dis-apply the legal restriction on the transplants of organs that involve a living donor, where it is satisfied that the conditions set out in the Regulations have been met. In short, the criminal offence that exists for living organ donors is only lifted when the requirements outlined below are met.

24. 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.

25. While the HTA must take the IA's report into account when making its decision on living donation cases; 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. This document sets out the circumstances under which additional information may be sought, and the forms that this might take. In all cases, the HTA will discharge its duties in line with the principles of best regulatory practice (transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

26. In reaching a decision about whether the HTA is "satisfied" in relation to the tests described in paragraph nine; the HTA, after taking legal advice, understands 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).

27. 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.

28. Section 32(11) of the HT Act creates the offence of payment or reward for organs intended for transplantation, from either living or deceased donors. Reward is defined as any "financial or other material advantage".

29. Further guidance on the interpretation of duress, coercion and reward, are provided in the section which describes the IA interview process.

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

Living donation concepts and definitions

31. 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 a number of different concepts in living organ donation.

Directed donation - A form of donation where a healthy person donates an organ to a specific identified recipient, with whom they have a genetic or pre-existing emotional relationship.

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 qualifying genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party - either a person or other mechanism, such as a social networking website which brings the donor and recipient together for the purpose of transplantation. For examples of directed altruistic donations, please see the table here.

Non-directed altruistic donation - A form of donation where a healthy person donates an organ to an unknown recipient, that is, someone they have never met and is not known to them [Regulations 12(5)].

Paired or pooled donation - A form of donation where a healthy donor is unable to (or chooses not to) donate because they are either incompatible by blood group or HLA (tissue) type, or would prefer a closer HLA match. They may be matched with another donor and recipient in the same situation in the

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 [Regulations 12(5)].

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

Domino donation - The HTA does not regulate domino donations. This is a further form of living donation in which an organ is removed for the primary purpose of a person's medical treatment. The removed organ may prove suitable for transplant to another person (e.g. a kidney that is removed as part of a person's treatment). Although this is classified as a living donation, the HTA does not regulate this because the donation arises from the patient's treatment.

32. The HT Act provides a list of qualifying relationships; these are:

- Spouse or partner
- Parent or child
- Brother or sister
- Grandparent or grandchild
- Niece or nephew
- Stepfather or stepmother
- Half-brother or half-sister
- Friend of long standing

33. If a donor and recipient have one of the relationships on this list, then the donation will be considered by the HTA Living Donation Assessment Team (LDAT). The HTA presumes that a case involving a donor and recipient with such a relationship will constitute a directed donation, as in the vast majority of instances, the donor and recipient will have had an emotional relationship prior to the need for a transplant arising.

34. If the donor and recipient have a genetic relationship which is not included on the list, for example, they are cousins; 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 for domestic donors or by the HTA panel, if the donor lives overseas.

35. **Overseas donor** - If a donor is a resident or a citizen of a country outside the UK, they will be considered as an overseas donor for HTA decision making purposes.

36. The table below provides information on the different types of cases, the definition and the responsibility, for decision making in each case.

Type of case	HTA definition	Case assessment
	Cases that are considered by the HTA living donation assessment team (LDAT)	
Directed kidney / liver donation between donor and recipient who are in a qualifying relationship	There is a genetic and/or established emotional relationship between donor and recipient.	A member of the HTA's LDAT will consider these cases for decision
Directed kidney / liver donation between donor and recipient who are in a non-qualifying genetic relationship	Donor and recipient are genetically related and have an established emotional relationship. Where there is no established emotional relationship, which is sometimes the case amongst, for example, cousins, then the case would be considered as a directed altruistic donation case. Example: Cousin	A member of the HTA's LDAT will consider these cases for decision If the donor is an overseas donor, a panel will consider the case for decision
Directed kidney / liver donation between donor and recipient who are in other forms of pre-existing relationship	Donor and recipient have had some form of pre-existing emotional relationship. Examples: Mother in law or father in law Brother in law or sister in law Co-worker	A member of the HTA's LDAT will consider these cases for decision
Directed altruistic cases – domestic donor *Non-qualifying genetic relationship and no pre-existing emotional relationship Or* *No pre-existing emotional relationship*	Donor and recipient have a non-qualifying genetic relationship and have no established emotional relationship and the donor is a UK resident. Donor and recipient have neither a genetic relationship nor a pre-existing emotional relationship, and the donor is a UK resident. Examples: Friend of a friend (may have an awareness of each other e.g. through a mutual person, but no relationship has been formed and there has been little or no contact / interaction). An organisation has campaigned for a donor (may have an awareness of each-other	A member of the HTA's LDAT will consider these cases for decision

	e.g. through a mutual organisation, but no relationship has been formed and there has been little or no contact / interaction). The donor has come forward after a media campaign, for example, after seeing the recipient's plight in a local newspaper (may have an awareness of each-other through the media campaign but no relationship has been formed and there has been little or no contact / interaction.	

Type of case	HTA definition	Case assessment
	Cases that are considered by a panel of three HTA Authority Members	
Directed altruistic cases – overseas donor *Non-qualifying genetic relationship and no pre-existing emotional relationship* *Or* *No pre-existing emotional relationship*	Donor and recipient have a non-qualifying genetic relationship and have no established emotional relationship, and involves a donor travelling from overseas. Donor and recipient have neither a genetic relationship nor a pre-existing emotional relationship, and involves a donor travelling from overseas. Example: Cousin who has come forward as a donor but has not had an active relationship with the recipient e.g. due to geographical location.	A panel will consider these cases for decision
Directed donation cases where there is an element of economic dependence (see examples opposite)	Donor and recipient have a non-qualifying relationship or are friends of long-standing, and the donor has a degree of economic dependence on the recipient. This category should be used at the discretion of transplant teams, depending on the facts of the case. We do not envisage those in qualifying relationships falling into this category; however, it may be relevant in some cases. Please contact the HTA Living Donation Assessment Team for further guidance on specific cases. Examples: The donor is either an employee of the recipient, or an employee of a friend of the recipient Potential concerns of these relationships could be that the donor may seek a reward	A panel will consider these cases for decision

	for the donation (either monetary or maybe a promotion at work). Also, the recipient may coerce the donor to proceed, by suggesting their continued employment is dependent on the donation. The recipient is the donor's landlord The concerns here could be that the donor may seek a reward for the donation (for example, living rent free for a period of time) or that the recipient may coerce the donor to proceed by suggesting the use of the property is dependent on the donation.	
Non-directed altruistic donation cases - kidney or liver	Donor comes forward to donate to an absolute stranger. The recipient will be identified from the national waiting list by NHSBT.	A panel will consider these cases for decision
Paired or pooled donation cases	Donor wishes to donate to an identified person but is unable to so or chooses not to, because they are either incompatible or prefer a better HLA or age match. Donor and recipient agree to be matched against other donors and recipients in the same situation in the Living Kidney Sharing Schemes. The donated organs are effectively swapped and each recipient in the pair or pooled donation group, is transplanted.	A panel will consider these cases for decision

Independent Assessors (IAs)

37. The HTA's role in living organ donation is to ensure there has been no reward sought or offered for organ donation, and to provide an independent check to help protect the interests of living organ donors. Thus, ensuring that each individual donor has an opportunity to speak freely to someone not connected with the transplant unit, thereby confirming that their wish to donate is free from any pressure to act against their will. IAs undertake interviews on behalf of the HTA to allow it to fulfil its role. IAs therefore play a key role in the system as a whole.

38. IAs must be independent of the living organ donation process and the donor and recipient. IAs are usually, but not exclusively, based in hospitals with transplant units or referring units.

39. It is very important that IAs bring an "independence of mind" to the IA interview, and that any information they might have heard prior to the interviews is put to one side.

40. Once trained and accredited by the HTA, IAs then 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 should remain strictly confidential between the IA and the HTA, and should not be shared with the clinical team.

The IA role

41. The role of the IA is defined in the Regulations (11(6)). IAs complete and submit a report to the HTA based on the evidence obtained in the statutory interview with the donor and the recipient. The HTA will then make a decision about the case based on the information provided by the IA, and any other relevant information gathered as part of its management of the case.

42. All IAs receive initial training from the HTA, and this allows them to conduct interviews for any type of case. In addition, the HTA provides IAs with online refresher training, which includes relevant case studies.

43. 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. The decision about whether a person is medically fit and suitable as a living organ donor is a matter for the practitioners concerned.

44. The referral letter should contain all the necessary information for comprehensive donor and recipient interviews to be carried out, including any risks that might be specific to the individual donor. A donor's capacity to consent on the removal of their organ is assessed by the Clinician responsible for the donor, and this must be confirmed in the referral letter to the HTA.

45. 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.

Resources required for the role

46. The resources required by IAs to carry out their roles should be provided by the Hospital Trust.

47. Ideally these resources should include:

- Time built into job plan / timetable;
- A room in which to see the donor and recipient;
- Payment by the transplant or referring unit for translating services, if required;
- Access to networked IT equipment;
- Access to IT scanning equipment;
- Somewhere secure to temporarily store notes from interviews, for example a lockable filing cabinet.

48. Once IA training has been completed, an enhanced DBS check will be conducted by the HTA. This certificate is considered valid for a period of three years. After this, it is the responsibility of the Hospital Trust to keep DBS checks up-to-date, and send a confirmation to HTA. In Scotland, all IAs must be immediately enrolled onto the Health Board's PVG scheme and a letter should be provided to the HTA as confirmation. IA training for delegates that have an existing DBS or PVG check dated within the last six months will be accepted by the HTA.

49. IAs conduct this legally required activity without resource allocation from the HTA.

50. It is recommended that any travel expenses that an IA incurs as part of this role, should be paid for by the Hospital Trust.

51. The HTA is not funded to remunerate IAs, and policies on IA remuneration differ. Any queries should be dealt with by the Hospital Trust.

Person specification

52. Before contacting a Living Donor Coordinator (LDC), individuals interested in becoming an IA must ensure they meet the person specification:

Skills

- Excellent oral and written communication skills;
- IT literate with an ability to grasp new systems;
- Excellent interpersonal skills;
- Confidence in interviewing people and exploring and addressing personal issues, such as health issues and health risks;
- Familiar with requirements to maintain patient confidentiality;
- The ability to work confidently in a hospital environment;
- Experience of report writing to a high standard;
- Familiar with equality and diversity legislation.

53. IAs come from varied backgrounds and do not need to be medically qualified. There is no requirement for IAs to work within a medical setting. Individuals may apply to be an IA if they have been, or expressed a wish to be, a living organ donor; they can also apply if they have received an organ. However, they must ensure that they do not seek to share their personal experiences and must remain independent.

Current IAs have professional backgrounds including:

- Healthcare staff from a variety of specialist backgrounds;
- Professionals allied to medicine;
- Hospital Chaplains;
- Retired healthcare staff - GPs, Senior Nurses and Surgeons;
- Retired professionals - Teachers, Judges and Police Officers.

54. If an individual is interested in applying to become an IA, but are unsure whether they meet the requirements above, they should contact their local LDC in the first instance. Contact details for LDCs are available on the HTA website (see useful links and resources).

Training and Accreditation

55. In order to be accredited, an individual must complete an application form and provide details of a referee to support their application (usually their Head of Department or Manager), and submit it to the LDAT, via a LDC. The HTA will only accept applications from people where an LDC has confirmed the need for additional IAs to be trained.

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

57. Following successful completion of the training, an enhanced DBS check will be carried out by the HTA.

58. Following the receipt of an enhanced DBS check, a certificate confirming accreditation will be issued, and a letter of confirmation sent to the individual. A letter will also be sent to the LDC, Clinical Director of the transplant unit, and Chief Executive of the Trust.

59. It is recommended that once accredited, IAs observe an IA interview with an experienced IA.

60. The HTA must be informed when an IA leaves the post. The HTA must also be informed if there are changes to an IA's contact details.

61. The HTA requires IAs to behave in a professional manner at all times. Complaints regarding IAs will be dealt with in line with the relevant HTA procedures.

62. IAs should be mindful of patient confidentiality – computers being used to submit IA reports should have appropriate network security, such as anti-virus software. When using a shared computer, care must be taken to ensure that the screen cannot be seen by others and IAs securely log out at the end of the session.

63. IAs must not provide a copy of the IA report to the clinical team, as it is a confidential report between the IA and the HTA.

Liability of Independent Assessors

64. 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 Living Organ Donation Assessment Process

Responsibilities of the Human Tissue Authority

Decision making arrangements

65. The HTA has a legal obligation to assess all of its referred cases. While some cases can be delegated to a member of the LDAT for decision, other cases are assessed by a panel of three Authority Members (panel cases). The HTA currently distinguishes two types of panel case:

- Panel cases by law, as described in the Regulations (12);
- Retained panel cases, where the Authority has decided to retain decision making responsibility and not delegate it to the LDAT.

66. Panel cases by law comprise of situations where:

- The donor is a child
- The donor is an adult lacking the capacity to consent
- Paired and pooled donations
- Non-directed altruistic donations

67. Retained panel cases are further divided into three sub-categories:

- **Directed altruistic donation cases with overseas donor** - These are cases where (a) the donation is being directed to a specific individual, (b) there is no evidence of a qualifying genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party (either a person or other mechanism) bringing the donor and recipient together for the purpose of transplantation) and (c) the case involves an overseas donor.

- **Economic dependence donation cases** - These are cases where the donor has no qualifying relationship with the recipient or is a friend of long-standing, and has some form of economic dependence on the recipient. For example, an employee or a tenant.

- **Cases which enter the regulatory decision making process** - These are cases where, having made an initial assessment of the IA report, the LDAT believes that rejecting the case is a possibility.

68. A table providing information on all types of cases and its corresponding HTA requirements, can be found here.

Responsibilities of Clinicians and Transplant Teams

69. The HTA recognises that particular living donation cases, or type of cases, will raise clinical and sometimes ethical issues. Clinicians and transplant teams are responsible for the overall care of donors and recipients, and for assessing the medical suitability of potential donors. The decision about whether a person is medically fit and clinically suitable as a living organ donor, is a matter for the medical practitioners concerned.

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

71. The Regulations require the clinician with responsibility for the donor, to refer the matter to the HTA for decision. The Quality and Safety (organs) Regulations place a set of further responsibilities on the referring clinician to provide certain specified assurances, and information to the HTA. The HTA has created a model referral letter template and issued guidance (see useful links and resources) for units to use, to ensure that all legislative requirements are addressed in the referral letter to the HTA.

72. It is HTA policy that all referral letters must:

- Be dated;
- Be on Trust headed paper, or contain the Trust logo in the header;
- Be signed (electronic signatures are acceptable);
- Use the following donation categories only: Directed, Directed Altruistic, Non-Directed Altruistic, Paired or Pooled Donation;
- Document the date of transplantation (if known);
- Document the wishes of the donor if their organ cannot be transplanted into their intended recipient.

73. All potential donors should be provided with a copy of the HTA leaflet, Our role in living donation and Guidance for living organ donors on the Human Tissue Authority's independent assessment process. Copies of these

documents are available to download in a range of languages from the HTA website (see useful links and resources).

74. The Guidance to transplant teams and Independent Assessors should not be read in isolation; there are other guidance documents on living organ donation which will be relevant to both clinicians and transplant teams (see useful links and resources).

75. The law requires that the HTA makes an assessment of any living organ donation application that is submitted to it. As a matter of either legislation or policy, certain activities need to be completed prior to the case being referred to the HTA. Please note that a case is considered to have been referred to the HTA at the point at which the IA receives the referral letter. The following sections will differentiate between the legal requirements, and policy matters.

Halted work-up

76. Occasionally, there are cases which are halted during the work-up process, and units take the decision not to proceed. These cases do not reach the stage of Independent Assessment. Some of these are halted for clinical reasons, but others may be halted for other reasons.

77. Presently, there are no national data collected on the reasons for halted work-ups. Working with the National Crime Agency, the HTA believes that clinicians have a duty to fill this gap: for example, cases where the halted work-up is a result of suggested organ and/or people trafficking for the purpose of organ donation.

78. Specifically, the HTA must be informed about cases where there has been an indication of:

- Reward (being sought by a donor)
- Reward (being offered by a recipient or third party)
- Duress (the donor being placed under pressure to donate - in Scotland, this also includes whether the recipient is being placed under pressure to accept the organ)
- Coercion (the donor being forced to donate)
- Verbal or physical threats towards the donor.

79. It is important to take into consideration, whether or not a case reaches the HTA for assessment: criminal offences may have been committed either under the HT Act, or people trafficking legislation.

Prevention of trafficking - both of human beings and of organs

80. The Council of Europe convention aims to combat trafficking in human organs. The term *trafficking* is defined as the illicit removal of organs, see below:

- Removal without the free, informed and specific consent of the living donor;
- In exchange for the removal of organs, the living donor or a third party, has been offered or has received a financial gain or comparable;
- Use of illicitly removed organs for the purpose of implantation or other purposes
- The illicit solicitation or recruitment of organ donors or recipients, by offering or requesting undue advantages (to/by health professionals or public officials)
- Preparation, preservation, storage, transportation, transfer, receipt, import or export of illicitly removed human organs
- Aiding or abetting and attempt.

81. For trafficking to have taken place, there must have been an Action, Means and a Purpose.

- **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 organs.

82. The below bullet points provide key indicators to be aware of during your contact with donors and patients:

- Is the person in possession of their own passport, identification or travel documents? Are these documents in the possession of someone else?
- Does the person act as if they were instructed or coached by someone else?
- Do they allow others to speak for them when spoken to directly?
- Is the person withdrawn or do they appear frightened?

- Is the person under the impression that they are bonded by debt, or in a situation of dependence?

83. Units must report any concerns of this nature to the HTA and, depending on the individual case, potentially refer the person to the National Referral Mechanism (NRM). The NRM is a process set up by the Government to identify and support victims of trafficking in the UK. It provides a framework for identifying victims of human trafficking and ensuring they receive the appropriate protection and support.

84. To be referred to the NRM, potential victims of trafficking must first be referred to one of the UK's two competent authorities - the UK Human Trafficking Centre or the UK Border Agency. The initial referral will usually be made by an authorised agency, such as a police force. For more information please click here.

Informed consent of the donor

85. Potential donors must be provided with sufficient information to reach an informed decision about whether they wish to donate an organ. This information should be provided by the transplant team before the IA interview.

86. If a donor lacks the capacity to consent, it is recommended that contact is made with the HTA in the early stages of the work-up to ensure that specific advice can be provided. It is also recommended that advice is sought from the Hospital Trust's legal team.

87. To ensure that informed consent is obtained, in both common law and the HT Act, the transplant team must make sure the following areas are fully discussed with the donor:

- The nature of the surgical / medical procedure and medical treatments that will be involved for the donor, as well as an explaination on the short and long term risks involved, which includes the risk of death (this should be explained by a medical practitioner with appropriate qualifications).

- The nature of any risks specific to the donor: perhaps the donor's clinical history predisposes them to a higher than average risk of developing a certain medical condition.

- The chances of the transplant being successful and any possible side-effects or complications, for both donor and recipient.

- The right to withdraw consent at any time before the removal of the transplantable material.

- The decision to donate must be free of duress or coercion.

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

88. The donor should have a clear understanding of the benefits and disadvantages of living donor transplantation in their particular case, as well as the general risks and benefits. Further information on this can be found in the British Transplantation Society (BTS) document, UK Guidelines for Living Donor Kidney Transplantation (see useful links and resources).

89. For potential non-directed altruistic and paired / pooled donors, the donor should also be informed of how the non-directed altruistic, paired / pooled process works, and how recipients are identified.

90. The donor and recipient should be made aware of the nature of the interview with the IA, and that a report will be submitted for decision by the HTA. Information should be provided to the donor and recipient on the areas which will be covered in the interview and the type of questions which might be asked.

91. The donor should also be given a copy of the HTA leaflet, *Our role in living donation, the "Guidance for living organ donors on the HTA independent assessment process* and the donor declaration form (see useful links and resources) in advance of the IA interview. Sufficient time should be given to the donor to read the guidance document and ask any further questions before the IA interview. The donor will be required to bring the donor declaration form to the IA interview. This can be signed either in advance of the interview, or at the interview.

92. To allow the IA to review the referral letter, it should be provided to the IA in advance of the interview, not on the day of the interviews.

Absence of a previously presumed genetic relationship

93. The HTA recommends that donors are asked to consider whether they wish to be informed if a presumed genetic relationship is revealed to be absent during the transplant work-up (see useful links and resources). The *UK Guidelines for Living Donor Kidney Transplantation* recommends that this matter is also explored with the recipient. However, as this aspect is outside of the HTA's remit, the approach to be taken, should be decided at a local level.

94. Relevant transplant teams decide on whether to proceed with a living donation when evidence shows that a presumed genetic relationship does not exist. This, in the experience of the HTA, is likely to require the involvement from the Hospital Trust's legal team.

Proof of identity

95. Written referrals must include confirmation that the LDC has informed the donor and recipient that they will be required to bring proof of identity to the IA interview, and that these should be original documents. This is to ensure the interviews are being conducted with the right people. Where original documents are not available, IA's should note this in their report to the HTA.

96. Documentation is required to verify the identities of donors and recipients. Passport, drivers licence or photographic identity cards are advised in all situations.

Evidence of relationship

97. Evidence of relationship is not applicable in cases of non-directed altruistic donation, although donors must be identified in line with the above section (paragraphs 95–96, proof of identity).

98. Evidence of relationship should be brought to the IA interview and confirmed in discussion with the IA.

99. If the donor and recipient claim a relationship but are not able to provide any documentary evidence, the LDC should contact the HTA for advice.

100. In cases of genetically related individuals where the relationship falls under the qualifying relationships list, but the donor and recipient do not have an emotional relationship; they should prove evidence of their genetic relationship where possible.

101. If the donor and recipient arrive for the IA interview without documentary evidence of their relationship and are presenting as a directed donation, it is important that the IA explores this with both individuals. The HTA can consider verbal evidence in some cases as evidence of an emotional relationship. This will be submitted to the HTA as a directed case.

Directed cases – evidence

102. For genetically related individuals, birth certificates of donor and recipient, and of other relatives where necessary; is to establish their genetic connection and should be provided as verification of their stated relationship. Where birth certificates are not available, alternative evidence could include one or more of the following:

- Family photographs spanning the duration of the relationship;
- Certified family tree;
- An affidavit attesting to the relationship;
- A statement / testimonial, ideally from an individual in a position of authority (e.g. lawyer, teacher, GP) who is able to attest to the validity of the relationship.

103. For emotionally related individuals, examples of documentary evidence could include, one or more of the following:

- A marriage certificate or certificate of civil partnership, should be provided where applicable;

- Proof of joint residence, such as utility bills or mortgage statements in joint names, where applicable;

- Photographs spanning the duration of the relationship;

- A statement / testimonial, ideally from an individual in a position of authority (e.g. lawyer, teacher, GP) who is able to vouch for the validity of the relationship. Otherwise statements from mutual friends or other similar relationships will be considered;

- An affidavit attesting to the relationship.

Directed altruistic cases – evidence

104. In order to identify whether a case fits the criteria of a directed altruistic donation, the transplant team should explore the nature of the relationship between the donor and recipient, and how the offer of donation arose. This should be confirmed in the referral letter.

105. Evidence of the relationship should be provided where possible: for example, in the case of cousins without an emotional relationship. However, in most of these cases; where the donor and recipient did not have a relationship prior to the arising offer of donation, means it is unlikely that there will be evidence of the relationship.

Donor declaration form

106. The HTA must ensure that safeguards are in place, to make certain that no reward has been, or is to be given, in contravention of section 32 of the HT Act (prohibition of commercial dealings in human material for transplantation).

107. All donors are asked to provide a signed declaration form, confirming the absence of reward for the organ donation and transplantation. The declaration should be read and signed by the donor, or person consenting on the donor's behalf; either in the IAs presence or provided to the IA (see useful links and resources).

Organs or part organs that cannot be transplanted

108. The following guidance only applies to directed, directed altruistic and paired or pooled donors. This guidance does not apply to non-directed altruistic donors. However, as good practice, these donors may be asked whether they would consent for their organs to be used in research, if they cannot be transplanted.

109. Donors should be asked during work-up, 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.

There are four potential options:

- Organ or part-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 paragraphs 113 – 117);

- 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.

110. The HTA must give separate approval in cases where the donor has consented prior to surgery, for the organ to be transplanted into an alternative recipient. 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 (see useful links and resources).

111. Donors who decide to have their organ re-implanted, must have an explanation from the clinical team about the possible risks associated with additional surgery. They should also understand the expected function of the organ after re-implantation.

112. If a donor has not made a decision at the time of referral, this should be documented under section five of the referral letter. If the donor is still undecided following the interview with the IA, the IA will need to record this in their report. The HTA will not make a decision on the case until the donor's wishes are known.

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

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

114. The decision about whether the secondary recipient is medically fit and clinically suitable, is a matter for the medical practitioners concerned.

115. The transplant unit or referral unit will need to arrange two IA interviews:

- With the donor and the primary recipient; and

- With the donor and the secondary recipient.

116. The same IA can carry out both interviews. The referral letter for both assessments should specifically document the re-direction request from the donor.

117. Before the IA assessments takes place, the clinical team would need to ensure that:

- the donor:
    - Is aware of the likelihood of an organ requiring re-direction;
    - Knows that they should also decide what they wish to happen in the event that their organ cannot be transplanted into the intended secondary recipient (the clinical team should discuss all options, as described in paragraph 109). This information will be recorded in the second IA report.

- the secondary recipient:
    - Is a suitable match to receive the organ, and;
    - Understands the circumstances under which they may receive an organ, and;
    - The likelihood of such an event.

Joint interviews

118. There may be a small number of exceptional cases of directed donation, or directed altruistic donation; where the donor and recipient do not wish to be interviewed together.

119. In these cases, the transplant team should contact the LDAT to make an application for the requirement of the joint interview being withdrawn. These applications will be considered by the Director of Regulation.

120. 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 donor and recipient.

Translators or other difficulties in communication

121. When a translator has been required in discussions between the transplant team and the donor and / or recipient, this should be referenced in the referral letter; so that the IA is aware that a translator will be required for the interview. Form HTA IT (DC) should also be completed and accompany the referral letter (see useful links and resources). Form HTA IT (IA) should be completed by the translator and given to the IA at the time of IA interview. Please note that the HTA IT (DC) or HTA IT (IA) forms do not need to be sent to the HTA.

122. In situations where a local independent translator is not available, a facility such as 'Language Line' can be used, provided a signed declaration form is obtained. In the case of someone with a speech or hearing disability, a translator should be used with experience in signing.

123. The translator should have no personal connection with either the donor or the recipient. The translator should have some understanding of medical matters, and should speak the donor's and recipient's language fluently.

124. A translator who is known to either the donor or recipient, should not be used in any circumstance. Translators should be independent of the donor and / or recipient. IAs can also act as translators, provided that they are fluent in the specified language.

125. IAs, in their report, should include any problems experienced with the quality of translation service provided. For example, where there has been a complaint that responses are being mistranslated.

Referral letter

126. The Regulations require that a medical practitioner with clinical responsibility for the donor, must have caused the matter to be referred to the HTA. The requirement of the Quality and Safety (organs) regulations makes it mandatory, that certain specified information is required from the referring clinician as part of this referral. Specifically, the referral must state that the medical practitioner, or person acting under their supervision:

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

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

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

127. As a matter of HTA policy, the HTA requests that referring donor clinicians also state that the medical practitioner is satisfied that the donor has capacity to consent to the donation. It is also requested that detail is provided on the recipient's capacity to participate in an interview to allow the IA to make any necessary adjustments.

128. The referral letter must include information about any risks specific to the donor, and confirmation that these have been addressed by the clinical team and are understood by the donor. This may include, for example, the donor having a higher than average risk of developing hypertension or diabetes post donation. Where no risks specific to the donor have been identified this should be stated in the referral letter. A model referral letter is available; please refer to the useful links and resources.

129. The referral letter should document any risks specific to the donor in a format which can be easily understood by the IA undertaking the assessment of the donor.

The referral process

130. The referral must be made by a registered medical practitioner, or a person acting under their supervision. The HTA considers a LDC to be a suitable person to make the referral.

131. The referral is made to the HTA at the point at which it is received by the IA; however the HTA cannot assess a case until it receives the IA report, referral letter and donor declaration. The referral letter must be provided to the IA in advance of the IA interview to enable the IA sufficient time to review these.

132. Referral letters and donor declarations must be sent to the HTA promptly after interviews have taken place. The referral letter and donor declaration should be scanned and sent with the IA report electronically to the HTA as

this is a more confidential, efficient and timely process. However, prepaid envelopes are available on request if needed.

Other considerations

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

134. Where the person who is donating is also the only suitable adult to accompany a child recipient to the IA interview, the transplant team should contact the LDAT for advice.

Out of hours service

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

136. This number is diverted to the on-call HTA representative. The transplant unit will be required to organise the IA interviews at short notice. The HTA representative will then assess the case and issue a verbal decision.

137. 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.

138. Such assessments often take place over the phone, and the IA will verbally report on the interviews to the HTA representative over the phone for a decision to be made. It is not required to email the referral letter or the donor declaration form to the HTA representative.

139. The IA will need to complete an electronic report at the first available opportunity (normally the following morning). All documentation should be submitted or uploaded at the time of submission of electronic report.

Private cases

140. Where a transplant takes place in the private sector, Clincians are advised to ensure that a LDC is involved (or equivalent role). This ensures that the donor has an advocate representing them that they can speak with who is

independent from the clinical team or Surgeon responsible for the care of the recipient.

141. It is important for the clinician to contact the HTA directly if they wish to seek advice and guidance regarding a specific donation.

142. IAs must remain independent, they should not have any involvement in the work up process of a donor and recipient.

143. The referral must be made by a registered medical practitioner, or a person acting under their supervision. Please see information about referral letters.

144. In terms of expenses, reimbursement guidelines of the Hospital Trust should be followed. The HTA advises that the clinicians refer to the NHS England commissioning policy for reimbursement of expenses to the living donor. The HTA may request to review the evidence of payment of reasonable expenses and the agreement as to the basis on which the recipient (or the family of recipient) is reimbursing expenses whether these are medical, travel, subsistence or accommodation costs.

Responsibilities of Independent Assessors

General requirements

145. The Regulations set out the requirement that the IA must have conducted 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. The purpose of this is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor's decision to donate and to explore the issue of reward jointly with the donor and recipient.

146. A recipient interview cannot be undertaken in cases of non-directed altruistic donation because there is no identified recipient at the time of the interview.

147. The Regulations detail the content of the matters to be covered in the reports on the interviews to be submitted by IAs. As a matter of policy the report must also contain an account of any relevant concerns the IA has which should contribute to the HTA's assessment of whether or not it is satisfied in relation

to the legal tests described at paragraph nine. Further information on the report section requirements can be found here.

Accepting referrals

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

- undertake the interview within one month of referral;
- submit their report to the HTA within 10 working days of the interview;
- be available following submission of their report (five working days for LDAT cases and 10 working days for panel cases) in case the LDAT needs further information or clarification.

149. It is important that annual leave arrangements are taken into account when scheduling interviews as delays may result in scheduled surgery not being able to proceed. If an IA considers they may not be able to undertake interviews, or submit reports within the above timescales, or they are on leave following submission to the HTA, it would be advisable to ask the transplant team to find an alternative IA for that case.

The Independent Assessor interview process

Interviewing donors and recipients

150. The interview should enable the HTA to ascertain whether the legal requirements have been met. The HTA system places the report of the IA interviews at the centre of our assessment process. We consider this to be the starting point for our assessment of a case, and if we cannot be satisfied on the basis of this, further investigations will be made. However, most cases are decided on the basis of the information contained within the IA's report.

151. The Regulations state that it is an IA's responsibility to interview the donor and recipient separately from each other. As a matter of policy the HTA also requires that the donor and recipient are interviewed together (with the exception of non-directed altruistic donation; and paired / pooled donation when the partner of the donor should be interviewed with them) as this provides an opportunity for the IA to witness how the donor and recipient

interact. This can often provide useful information which contributes towards an understanding of the likelihood that the legal tests have been satisfied.

152. When a case is referred to an IA, the IA should familiarise themselves with the information provided in the referral letter and check if the transplant team has assigned the correct donation category to the case and that any risks specific to the donor have been documented. If there are any discrepancies, or if anything is unclear, the IA should contact the transplant team to clarify.

153. There may be a small number of directed donation, or directed altruistic donation, cases where the donor and recipient do not wish to be interviewed together. The transplant team may have sought permission from the HTA for the requirement for the joint interview to be withdrawn. This should be reflected in the referral letter to the IA and indicated by the IA in the report to the HTA. If such permission has not been sought the IA should proceed with a joint interview.

154. While the donor and / or recipient may request that a third party sits in on the interview to provide support, the third party should not be responding to questions on the donor or recipient's behalf. 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. The IA should make a note in the IA report regarding presence of third party and whether any or all questions were answered by the donor.

If the recipient is a child

155. If the recipient is a child, 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 could be considered.

156. A situation should not arise where the IA is alone in a room with a child recipient. When the recipient is a child then it is appropriate for an adult to accompany them, although the interview itself should be with the child and not the adult. If this is not possible then the IA should contact the HTA prior to the interview to discuss the options available.

157. The IA should always endeavour to conduct an interview with the child. If the child is too unwell to be interviewed, pre-verbal or not willing to talk to the IA, then the IA should decide if it is proportionate to undertake an interview with the child and record this information in the report. There is no legal requirement for someone to be interviewed on behalf of a child recipient.

158. For directed altruistic donations, where the child is a recipient, the HTA considers it good practice for the IA to meet with the recipient's parent to help build an understanding of how the donation came about as well as exploring duress, coercion and reward.

Other Scenarios

159. In cases of non-directed altruistic donation, only the donor needs to be interviewed.

160. There may be occasions when either the donor or 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. In such circumstances the IA interviews should not be attempted and contact should be made with the transplant team to discuss and reschedule where appropriate.

161. There may be occasions during interviews where inconsistencies arise in the donor and recipients account of relevant facts. In each situation it is a judgment about how to explore the inconsistencies. It is appropriate for the IA to either explore this by directly questioning the inconsistency, or the IA may judge it best to probe further into the detail with both the donor and recipient accounts separately. It is important for IAs to include in their report any differences in relevant facts and how it was explored.

162. If during the course of the interview there is an indication that either the donor or the recipient, or both, may not have capacity, then this should be noted in the report. The IA should also contact the HTA after to the interview to discuss.

Interview content – donor and recipient

Any evidence of duress or coercion affecting the decision to give consent

163. 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 then their consent may not be valid, and if they are only donating because of this pressure then their consent would certainly not be valid. The HTA cannot approve a living donation case if the consent of the donor is not in place.

164. 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 interview and make a note of these issues in the 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.

Any evidence of an offer of a reward

165. Reward, in the context of the HT Act, is a financial or material advantage which induces a person to become a living donor. In practice, reward means any money, gift or other benefit with a financial value which influences the decision to donate an organ.

166. The interview, therefore, must explore the extent to which there is any reward linked to the donation.

167. 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.

168. It is recognised that this is a complex area and it is important that during the IA interviews 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.

169. 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 should be provided in the report.

170. It is 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.

171. The decision on whether a reward 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 both the issues of whether any reward exists, and the bearing this has had on the donor's decision to go ahead.

172. The HT Act permits donors to receive reimbursement of reasonable expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation.

173. The reimbursement of reasonable expenses incurred as a direct result of living donation in England will be made directly by NHS England (other UK countries have adopted similar processes to mirror this). However, the NHS is not obliged to make such payments. Reimbursement of reasonable costs can also be made by other people and organisations. More information about reimbursement of expenses for living kidney donors in England is available here.

174. It is acceptable for a recipient (or the family of the recipient) to directly reimburse reasonable expenses incurred by the donor, if circumstances necessitate this. In this circumstance 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.

175. Further information on the reimbursement of living donor expenses can be found in the BTS *UK Guidelines for Living Donor Kidney Transplantation* (see useful links and resources).

176. As referenced at paragraphs 106-107, the donor is required to sign a declaration confirming there is no reward associated with the organ donation and transplantation. A copy of the declaration form is available from the useful links and resources section.

Interview content – donor only

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

- The information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the

transplantable material (this must cover both general risks and those speicific to that donor);

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

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

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

178. The donor may inform the IA during interview that they wish to withdraw their consent and not proceed with the donation. In the first instance the IA should ask the donor whether this is something they feel able to discuss with the transplant team. If this is an option, then the IA should support the donor in communicating this to the transplant team. The referring clinician should halt the work up and withdraw their referral to the HTA. The IA report should be submitted in the usual way, but the HTA would not be required to make a formal decision if the referral has been withdrawn.

179. If the donor withdraws their consent but does not wish to communicate this to the transplant team, then the interview should continue and a full report be submitted to the HTA. It is not for the IA to communicate with the transplant team or the recipient that the donor wishes to withdraw their consent, and this information should only be communicated to the HTA. In such circumstances the HTA would be obliged to make a decision on the case.

Interview content – recipient only

180. The Regulations require that the report on 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 transplantable material 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 material for the purposes of transplantation.

181. The recipient interview should also cover any evidence of reward and any difficulties in communicating with the recipient and how these were overcome.

182. The referral letter from the clinician should highlight any issues relating to the recipient's capacity to undergo the interview. In general terms, the IA should undertake, or attempt to undertake, an interview with the recipient. There are some exceptions to this:

- Where the recipient unarguably lacks capacity, for example if they are a baby or pre-verbal child, then attempting an interview would be disproportionate and result in unnecessary use of resources. Similarly, there may be other unusual circumstances where it is not in the interests of the recipient to be interviewed.

- Where there is an indication that the recipient lacks the capacity to be interviewed, then the IA should seek further guidance from the HTA on whether to attempt an interview, or the adjustments that should be made in order to undertake an interview.

183. In all circumstances, whether or not an interview is attempted, the IA should provide a report of the recipient interview, commenting on capacity problems under the provision of the Regulations relating to communication difficulties and how (where possible) these were overcome. This section of the report may, under certain circumstances simply report that no interview was attempted and the reasons for this.

184. If the interview is undertaken and, as a result of the recipient's lack of capacity, elicits no information relevant to the HTA's requirements, then this should also be reported here. If the interview does illicit information relevant to duress placed on the donor, or evidence of reward, these should be reported in the relevant sections of the IA report.

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

Welfare or safeguarding issues

186. If during the assessment, 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.

187. IAs should familiarise themselves with the hospital Trust safeguarding policies.

Other requirements for the IA report

188. 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 in relation to the legal tests described at paragraph nine.

189. In cases of paired / pooled donation the following additional points should be explored:

- Ensure the donor and partner are fully aware of the matching process involved and that they are aware of the implications and risks; for example, the donor may donate but there is a risk their partner may not receive a kidney in return. More information can be found in the NHSBT leaflet *Living Kidney Sharing Schemes* (see useful links and resources).

190. In cases of non-directed altruistic donation, clinical teams must ensure the donor is aware of the meaning of non-directed organ donation, that they understand how the recipient is identified, that they will not know who receives the organ and that they may never know the recipient's identity. More information can be found in the NHSBT leaflet *Living Kidney Sharing Schemes* (see useful links and resources).

Completing and submitting the interview report

191. Following an interview, IAs should submit a report of their interview to the HTA within ten working days. If for any reason the report cannot be submitted within ten working days, the IA should inform both the clinical team and the LDAT.

192. The HTA has a secure online portal accessed via the HTA website, for the submission of IA reports. The system allows IAs to write reports electronically and save them as frequently as they wish before submitting to the HTA. Copies of documents required by the HTA can be uploaded with the report (referral letter and donor declaration). Separate guidance is available for IAs using the portal which is available on the HTA website (see useful links and resources).

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

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

Report section guidance

Report section	**Mandatory information**
Section A – Category of transplant	In this section, IAs are asked to 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. Therefore, if there are any concerns about the category of donation mentioned in the referral letter, please contact the transplant team and HTA to clarify any issues.
Section B – Details of donor, recipient (or partner) and location of transplant	Details on the donor, recipient (or partner) and units must be entered here. If there are two LDCs in a unit, please include both their names to make sure the approval is sent to both. Only establishments licensed under the *Quality and Safety (organs) regulations* will be listed here. If an establishment or contact is not appearing in the list, please contact the LDAT.

Section C – Evidence of identity and status of relationship	IAs must confirm they have seen suitable identification to ensure they are interviewing the right people, or provide the reasons why this was not possible. Evidence of the relationship must be confirmed by the IA and indicated in this section. A drop down list of relationships is provided. If these options are not appropriate, IAs can select 'other' and write the relationship. *This section is not relevant for non-directed altruistic cases.* For directed altruistic donation cases, IAs must provide information on how 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	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	This section should be used to highlight any communications difficulties with those interviewed and how any communication difficulties were overcome.
Section F – Understanding of the nature of the procedure and the risks involved	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 should be explored with the donor in the interview. The IA must provide information that the donor understands any risks specific to them. The IA must confirm that mandatory information was included in the referral letter. The medical practitioner's details must also be provided in this section. The IA must confirm that the donor understands that that are able to withdraw consent and does not wish to do so at present. 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 in the unlikely event it cannot be used for the intended recipient, 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. The IA is asked to confirm that the donor and recipient (or partner) were seen separately and together. This information is crucial as it goes towards the HTA's judgement of whether valid consent is in place.
Section G – In directed cases, section G is on duress, coercion and reward For non-directed cases, section G asks the IA to confirm that the donor is aware of the implications of being a non-directed altruistic donor and understands the process. For paired / pooled cases, section G asks the IA to confirm that the donor is aware of the implications of being a donor in the paired / pooled scheme and understands the process.	**For directed cases, section G is on duress, coercion and reward.** 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.

	The report must contain any evidence of duress or coercion or reward affecting the decision to give consent. There must be sufficient evidence for the HTA to exercise an independent judgement. This evidence can 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. The IA must also include their observation of the pair in the joint interview, you may comment on how the offer of donation came about and the body language and interaction between the donor and recipient. It 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 we can be satisfied that that no reward has been or is to be given and that there is no duress or coercion IAs must also confirm if they have received a signed donor declaration or the reasons why this has not been provided to the IA by the donor. 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. This is the end of the report for directed cases.
	For non-directed altruistic cases, section G requires the IA to confirm that the donor is aware of the implications of being a non-directed altruistic donor and understands the process. The IA is asked to confirm that the donor understand the process that they will be either donating to the deceased donor waiting list or starting a non-directed altruistic chain.
	For paired / pooled cases, section G requires the IA to confirm that the donor is aware of the implications of being a donor in the paired / pooled scheme and understands the process.
Section H – In non-directed altruistic donations and paired / pooled donations, this section covers duress, coercion and reward	**For non-directed altruistic cases, section H requires the IA to** 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. IAs must also confirm if they have received a signed donor declaration or

	the reasons why this has not been provided to the IA by the donor. 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. This is the end of the report for non-directed altruistic cases.
	For paired / pooled cases, section H requires the IA to 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. IAs must also confirm if they have received a signed donor declaration or the reasons why this has not been provided to the IA by the donor. IAs are also given an opportunity to provide information on any other issues that should be brought to the HTA's attention which may be relevant during the case consideration process and have not been covered elsewhere in the report. This is the end of the report for paired /

	pooled cases.
Section G/H Any other issues that you wish to draw our attention that you believe may be relevant to our decision in this case which are not covered elsewhere in the report?	The IA should inform the HTA on anything that has not been captured elsewhere e.g. feelings of concern.

195. The referral letter and donor declaration should be scanned and sent with the IA report electronically to the HTA as this is a more confidential, efficient and timely process. However, prepaid envelopes are available on request via transplants@hta.gov.uk for those without scanning facilities. If documents are being sent in the post they must be sent immediateoy after the IA interviews.

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

197. 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) to enable access to the decision when one person is on leave or unexpectedly absent.

Contingency report system

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

- if the system cannot be accessed, IAs should retry after a few hours and if still unavailable contact the HTA;
- 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 (see useful links and resources).
- The report should then be submitted by email to transplants@hta.gov.uk with IA report in the subject line.
- If a report cannot be received or submitted by email, a copy should be sent to fax number 020 7269 1997, it is important that the HTA is

contacted before the fax is sent to confirm that this can be securely received.

199. There is no time limit on the validity of an approval. However, if the circumstances of the donor and / or recipient change during the time between HTA approval being granted and the transplant going ahead, and this period is more than 12 months, the transplant team should contact the HTA for advice on whether a further independent assessment should be undertaken.

Case review by the HTA

Cases assigned to the LDAT for a decision

200. Once the HTA receives a case from an IA, this will be assigned to a member of the LDAT. A general check of the report will be carried out to ensure that all required sections have been completed and the referral letter and donor declaration form have been received. The case will then be considered for decision.

201. If information is unclear or is missing from the report, the IA will be contacted for further clarification. When the HTA ask for more information, we are not questioning the judgement of the IA; we are simply gathering minimum evidence to make a lawful decision.

Cases assigned to an Authority panel for a decision

202. Once the HTA receives an Authority panel case from an IA, a member of the HTA LDAT will undertake a general check of the report to ensure that all required sections have been completed and the referral letter and donor declaration form have been received. If information is unclear or is missing from the report, the IA will be contacted for further clarification.

203. A panel will be convened and the case will then be considered for approval.

204. If a panel of three Authority Members cannot reach a unanimous decision, the panel may reach a majority decision.

205. If there is insufficient evidence for the Authority to be satisfied, in line with the Regulations 11(3), the HTA may not approve a case. However, it is the policy of the HTA to seek further information, where possible, in order to be satisfied of the legal requirements.

Case review meetings

206. A case review meeting will be convened, if any of the contents of an application give rise to concerns that:

- there are questions about the donor's capacity to consent;
- there are indications that the donor is being coerced or is under duress;
- there is any indication that reward has been offered, given, sought or received; and
- IA comments indicate any unease with the application.

207. A Case Review Meeting exists to decide what further action needs to be taken in order to allow the case to proceed, or for a Regulatory Decision Meeting to be held.

208. A Case Review Meeting will be attended by the Director of Regulation, the LDAT and members of the panel. One aim of the meeting will be to identify any further evidence that the HTA should seek in order to enter the Regulatory Decision Meeting – this could include, but is not limited to:

- further discussions with the LDC or the IA;
- the decision to undertake a further directed IA interview with the donor, the recipient or both;
- the decision to interview the donor, the recipient or both directly; or
- a request for further supporting documentation.

Regulatory Decision Meeting

209. A Regulatory Decision Meeting will be convened once the actions agreed at the Case Review Meeting have been completed.

210. Attendees at the Regulatory Decision Meeting will be the same as those at the Case Review meeting, plus an external legal adviser. The aim of the meeting is to make the decision whether to approve or reject the application. A panel will always make the decision in cases that require a Regulatory Decision Meeting.

211. Where there is insufficient evidence for the HTA to be satisfied that the donor has capacity to consent, the HTA may refer the case back to the medical practitioner, who will be asked to provide the evidence underpinning their assessment described at paragraph 126.

Service standards

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

213. Panel cases received by 09.00 on a Monday morning will be referred to panel on the Wednesday of that week. Panel cases received after 09.00 on a Monday morning will be referred the following week.

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

Other considerations

Cases where approval cannot be given

215. In cases where the requirements have not been met and the HTA turns a case down, the donor, recipient, and medical practitioner with responsibility for the donor will be notified in writing and provided with reasons for that decision. The letter will also outline the procedure for reconsideration of the decision.

Reconsiderations (Appeals)

216. Once the HTA has given approval for a transplant operation, it will have done so on the basis of being satisfied that the legal tests have been met, as well as being satisfied that there is no other legal reason that would make the surgery unlawful. If the Authority receives evidence between giving approval and the surgery that could affect the test of being satisfied, then it has power under the Regulations (13) to reconsider the case and make a fresh decision.

217. 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 [Regulations 13(1)]. The Regulations (14) require that reconsideration is made as a fresh decision at a meeting of the Authority and that any members involved in the original decision are disqualified from participation in the fresh decision. Depending on the facts of the case, further information may be required from the donor and / or recipient in order to reach a decision.

218. The Regulations also allow specified persons, listed below, to request a reconsideration of a decision of the HTA. For reconsiderations initiated by specified persons [Regulations 13 (2) and (3)] the reconsideration will be managed in line with the appropriate Standard Operating Procedure.

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

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

Useful links and resources

Human Tissue Authority resources

Leaflets	Information about living donor transplants https://www.hta.gov.uk/our-role-living-donation
Guidance	Guidance for living organ donors on the HTA independent assessment process https://www.hta.gov.uk/guidance-public/living-organ-donation/guidance-donors-our-processes Guidance for using the portal https://www.hta.gov.uk/policies/information-about-hta-portal-ias-including-login IA reaccreditation and performance assessment process https://www.hta.gov.uk/ia-re-accreditation-and-performance-assessment-process-0 HTA Codes of Practice: https://www.hta.gov.uk/guidance-professionals/codes-practice Organs Intended for Transplantation – documentary framework https://www.hta.gov.uk/sites/default/files/HTA-GD-014%20-%20Organs%20Intended%20for%20Transplantation%20-%20documentary%20framework.pdf
Forms	Independent Assessor application form https://www.hta.gov.uk/sites/default/files/Independent%20Assessor%20application%20form-%20PDF%20version_editable.pdf Independent Assessor Contingency Report https://www.hta.gov.uk/sites/default/files/IA_Contingency_Report.pdf Donor declaration form https://www.hta.gov.uk/policies/donor-declaration-forms Translation Declaration Form (Form HTA IT (IA)) https://www.hta.gov.uk/sites/default/files/migrated_files/Form_HTA_IT_%28IA%29.pdf

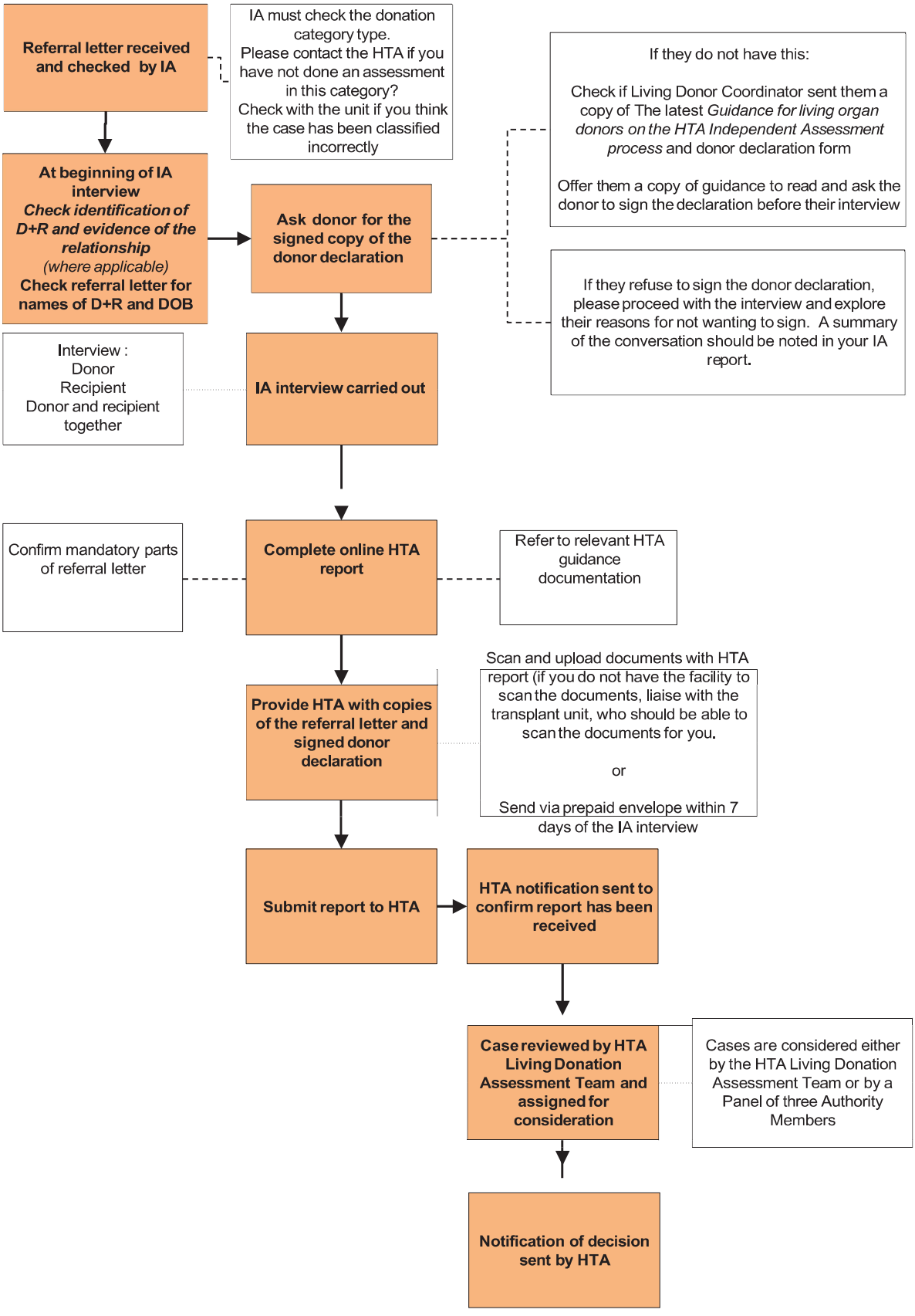
Contacts	Contact details for transplant units and LDCs https://www.hta.gov.uk/guidance-public/contact-details-transplant-units

External resources

Leaflets	UK Living Kidney Sharing Schemes https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1432/27514-uk-living-kidney-sharing-schemes.pdf Could I be a living kidney donor? https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1433/1617-234-could-i-be-a-living-kidney-donor.pdf Can I donate a kidney to someone I don't know? https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1434/27513-donating-to-someone-unknown.pdf NHSE commissioning policy for reimbursement of living donor expenses https://www.england.nhs.uk/wp-content/uploads/2017/08/comm-pol-reimbursement-expenses-living-donors.pdf
Guidance	British Transplantation Society UK Guidelines for Living Donor Kidney Transplantation http://www.bts.org.uk/transplantation/standards-and-guidelines/ Council of Europe Convention on Action against Trafficking in Human Beings https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236093/8414.pdf
Toolbox on Kidney Living Donation	http://ec.europa.eu/health/blood_tissues_organs/docs/eutoolbox_living_kidney_donation_en.pdf
Legislation	Human Tissue Act 2004 http://www.legislation.gov.uk/ukpga/2004/30/contents Human Tissue Act 2004 (Persons who Lack Capacity to

	Consent and Transplants) Regulations 2006 http://www.legislation.gov.uk/uksi/2006/1659/contents/made The Quality and Safety of Organs Intended for Transplantation Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1501/contents/made The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 http://www.legislation.gov.uk/uksi/2014/1459/contents/made Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/contents Mental Capacity Act code of practice 2005 http://www3.imperial.ac.uk/pls/portallive/docs/1/51771696.PDF Mental Capacity Act (Northern Ireland) 2016 http://www.legislation.gov.uk/nia/2016/18/contents Human Rights Act 1998 http://www.legislation.gov.uk/ukpga/1998/42/contents
Charities and sources of information	The following resources may be useful for potential donors: Living Kidney Donation http://livingkidneydonation.co.uk/ Give a Kidney http://www.giveakidney.org UK National Kidney Foundation https://www.kidney.org.uk/

Independent Assessor quick reference process flowchart



ANNEX A

General guidance on interview techniques and report writing for Independent Assessors

This guidance can be used by Independent Assessors when interviewing donors and recipients, and when completing reports. It is not meant to be prescriptive; however, it does contain good practice guidance on the areas of reports where the HTA most often has to seek further information.

Section F: Please provide full details of the donors understanding and acceptance of the nature of the procedure and the risks involved in donating an organ.

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.

Below are some questions which will help ensure all the essential information is included:

- Have I included the donor's understanding of the surgical procedure? This should include the donor's description of the type of surgery they are expecting to have eg laporoscopic.
- Have I included whether the donor confirmed they understand that there is a risk of death occurring?
- Have I included other risks that the donor mentioned and confirmation that the donor understands any risks specific to them?

PLEASE NOTE: 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. If donors have any questions about the surgery or risks, it is important that you refer them back to the Clinician.

If for some reason the donor is unable to recall the risks or nature of procedure, please mention it in your report so the Living Donation Assessment Team can liaise with the clinical team.

EXAMPLE ANSWER FOR KIDNEY

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.

EXAMPLE ANSWER FOR LIVER LOBE

I asked the donor to outline what she understood about the procedure. She said it will be a major operation where the doctors will make an L shaped incision in her abdomen; she pointed to where the incisions would be on her body. She said they will then 'cut off' a lobe of her liver.

I asked her if she was aware of the risks associated with having this procedure and she said yes. She went on to say she is aware that she could die and that the statistic is about 1 in 200 as she is donating to an adult.

I asked her if she knew of other risks and she said yes; she is aware she could bleed and may require a blood transfusion. She said she could develop an infection or a clot in one area of her body that could travel to other areas and cause further complications. She said she knows there could be bile leakage and that she will be left with a large scar. She has thought long and hard about her decision and has done her own research in addition to listening to the details the staff at the unit have provided. She accepts all these risks and wishes to proceed.

Section H: Duress, Coercion and Reward

Please provide full details of the discussion had with the donor 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.

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 that this is not the case. IAs must report explicitly that they have asked direct questions of the donor and recipient in each of these areas and what the responses to the questions were.

Interview techniques to approach the subject of duress and coercion

- *put open questions to both the donor and recipient about how the offer of donation came about;*

- *talk to the donor about their motivation to donate;*

- *explicitly ask the donor and recipient whether anyone has placed them under duress or coercion to proceed to donation; and*

- *if you feel that duress or coercion may be a factor in the offer of donation it is important that you thoroughly question both the donor and recipient on this subject both together and separately to ensure they are both consistent.*

EXAMPLE ANSWER

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 has said that she has not put the donor under any pressure and confirmed that the donor offered to donate of her own free will. The donor confirmed that in her discussions with me. 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. The donor is acting entirely voluntarily.

The Human Tissue Act creates the offence of payment or reward for organs intended for transplantation from either living or deceased donors. Reward is defined as "any financial or other material advantage". A payment of money will constitute reward even if it is of a trivial sum because the word "material" only refers to the word advantage.

Interview techniques to approach the subject of reward

- Talk to the donor and recipient about the donor declaration on reward when checking that it has been signed. Using the donor declaration is a good way to broach their understanding of what reward is and whether there is any reward involved;

- it should not be assumed that reward is not a factor because the donor has shown other motivations to donate, even between close family members and

friends;

- donors and recipients should be asked explicitly if there is any offer of reward and IAs should report on the response from each in their report;

- If you feel that reward may be a factor in the offer of donation it is important that you question both the donor and recipient on this subject both together and separately to ensure they are both consistent

For more information on what constitutes reward please refer to paragraphs 165-176 in the main guidance.

Please provide full details of the discussion had with the donor and recipient / partner (where applicable) in order to determine (as far as possible) that there was no evidence of an offer of a reward that would affect the donor's ability to give consent.

EXAMPLE ANSWER

I explicitly asked both the donor and recipient if there was any reward involved in the donation and they both confirmed to me today that the offer was entirely voluntary on the donor's part 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 laughed and replied 'No, not at all – he is donating purely to try and make me better. I have nothing to offer anyway, he is the breadwinner and our income is shared'.
I can confirm from my discussions with both donor and recipient that there is no evidence at all that the donor expects 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.

HTA guidance: example questions for IAs conducting interviews

The purpose of this section is to provide some example questions to support IAs with the statutory interviews. These examples should assist with interviewing the donor and recipient separately, as well as the joint interview with the donor and recipient. These are designed to explore whether there is any evidence of duress, coercion and reward.

Donor Interview

Exploring how the donor has made the decision to donate

1. Can you tell me about your motivation and reasons for donating?

2. Can you tell me how you reached this decision?

3. How do you feel about donating your organ?

4. Are you aware that you can change your mind at any point - has this been explained to you?

5. Do you understand that you can change your mind at any point during this process if you feel unsure? Would you feel able to do so?

Exploring duress/coercion

6. Has anyone put any pressure on you to donate (including the recipient or any other person)?

7. Do you feel that you are under any obligation (i.e. that you must) to proceed with this donation?

8. Has anyone, including the recipient or any other person, put pressure on you to go ahead?

9. Would you feel able to pull out of the process if you wanted to do so?

Exploring reward

10. Have you completed a donor declaration form that confirms that you have not received any offer of reward?

11. Has anyone promised you an offer of reward, either monetary or a gift, if you donate?

12. Is there any payment of money, or any other kind, involved in this donation?

13. Do you understand that is it illegal to offer or receive payment or any other reward in exchange for an organ?

Recipient Interview

Exploring duress/coercion

14. Do you think that the donor feels under any pressure to donate?

15. Do you feel that the donor may feel they have no option but to proceed with this donation?

16. Do you think that the donor is being forced to donate?

17. Have you placed any pressure on the donor to proceed with this donation?

18. How would you feel if the donor changed their mind?

Exploring reward

19. Have you, or any else, promised the donor a reward, either monetary or a gift, if he/she donates?

20. Is the donor being rewarded for this donation, this could mean money or any other gift?

Joint Interview

Exploring duress, coercion and reward jointly

21. How do you both feel about proceeding with this donation?

22. Do you feel that there is any pressure from anyone to proceed with this donation?

23. Has there been any offer of reward, or any other gift, promised for this donation?

24. Are you aware that the donor can withdraw their consent at any point before the operation without giving a reason?

Exploring economic dependence

Directed cases where the relationship have an element of economic dependence include donors and recipients who have a non-qualifying relationship or are friends of long-standing and the donor has a degree of economic dependence on the recipient.

The most common examples include:

- The donor is an employee of the recipient; or
- The recipient is the donor's landlord.

For more detailed information please refer to page 14 of the guidance document.

Where the donor is an employee of the recipient:

25. How long have you worked for the recipient?

26. What are the arrangements for pay during your recovery period - will this be statutory or other?

27. Do you think that you may benefit at work from proceeding with this donation?

28. Do you feel worried about your employment if you no longer wanted to proceed with the donation?

29. Has there been any suggestion from the recipient, or anyone else, that your living arrangements would change if you didn't go through with the organ donation?

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