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Guidance to 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. Also, where this document refers to adults who lack capacity this also includes children who do not have competency.

2. This guidance, along with the Documentary Framework for the Quality and Safety of Organs Intended for Transplantation, supplements the HTA's code of practice on the Donation of solid organs for transplantation (code 2).

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 for the removal, storage and use of human organs and tissue from the deceased. The HT Act covers England, Wales and Northern Ireland.

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 person commits an offence if they remove or use 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 (SI 2006 no. 1659) (Transplant 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 dis-applied.

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 17).

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 Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (referred to in the rest of this document as the Regulations) is the secondary legislation that sets out the legal requirements that must be met in order for the HTA to give approval for living organ donations.

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

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

10. The HTA also assesses living organ donation cases on behalf of the Scottish Government. This document describes the way in which the HTA applies the HT Act and the Regulations, and the approach described applies throughout the United Kingdom. Where there is a difference in the legislation that affects how the HTA assess a case, this is explained in the document.

The Scottish Legal Framework

11. 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)).

12. In Scotland the word “authorisation” is used rather than “consent”, however, the principle remains the same. When consent is referred to in this document, it means both consent and authorisation, unless otherwise specified.

13. Scottish law distinguishes three broad categories of potential donors: adults (those aged 16 and over) who have the capacity to make their own decisions; adults who lack that capacity; and children (those who have not yet reached the age of 16). There are restrictions on each in terms of living donation, and the Regulations (Scotland) set out the circumstances in which those restrictions can be lifted by the HTA.

14. The common requirements in each of these categories are that the HTA has to be satisfied that:
no reward has been or is to be given in contravention of section 20 of the HT (Scotland) Act, which prohibits commercial dealings in parts of a human body for transplantation;
there is no evidence of duress or coercion affecting the donor’s decision; and
the relevant requirements of the Regulations (Scotland) under the HT (Scotland) Act have been met.

15. For adults with capacity, the requirements in addition to those described above, are as set out in this guidance document. Where there are slight differences relative to the rest of the UK, these are identified in the text.

16. Adults with incapacity and children can only donate an organ, or part of an organ, which has to be removed as part of a domino organ transplant operation (further information on page 11), or regenerative tissue. Units and IAs managing cases with donors in these categories should approach the HTA for further guidance on additional requirements in these cases.

17. 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 to equivalent cases in the rest of the UK.

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


19. The HTA has published a Documentary Framework for the Quality and Safety of Organs Intended for Transplantation, and this should be consulted for information and guidance on licensing requirements and standards.
20. The Human Tissue Authority must consider other legislation when carrying out its duties. The Mental Capacity Act (MCA) 2005, the Adults with Incapacity (Scotland) Act 2000 and the Human Rights Act (HRA) 1998, in particular, have bearing on the way the HTA conducts its role. In addition, the HTA must act in accordance with public law principles. These obligate the HTA to act within its lawful powers, to act reasonably and to follow fair procedures.

21. By law, the HTA has a role to ensure that individuals only make donations if they have capacity (in the case of adults) or competency (in the case of children), that they have made an informed and voluntary decision, free from duress and coercion, after receiving proper medical advice; and 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 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

22. 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, including for the purpose of transplantation.

23. 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. The current HTA codes cover the following topics:

1. Consent
2. Donation of solid organs for transplantation
3. Post-mortem examination
4. Anatomical examination
5. Disposal of human tissue
6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
7. Public display
8. Import and export of human bodies, body parts and tissue
Overview of the regulatory framework for living organ donation

24. Regulation of living donation in the UK exists to ensure that donors are not forced to do something against their wishes and to ensure that there is no trafficking in organs. By extension, regulation also exists to safeguard against people trafficking for the purposes of organ donation. In this way, regulation acts as a mechanism to ensure that these are not factors in each individual case of living donation and, more broadly, to act as a deterrent to these practices.

25. The regulatory requirements for living donor transplantation are set out in the HT Act, the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (SI 2006 no. 1659) (the Regulations) and the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (Regulations (Scotland)).

26. The Authority’s role is to dis-apply the legal restriction on transplants of organs involving a living donor where it is satisfied that the conditions set out in the Regulations or the Regulations (Scotland) have been met. That is to say, the criminal offence that exists for living organ donors is only lifted when the requirements outlined below are met.

27. Specifically, the Regulations require that:

- A registered medical practitioner with clinical responsibility for the donor must have arranged to refer the 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 Authority 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 Regulations (Scotland) require that the Authority be satisfied on all matters covered in the reports from Independent Assessors.

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

- The Authority must give notice of its decision to the donor, the recipient and the referring medical clinicians [Regulations 11(5)].

- The Authority 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. Guidance on consent under the HT Act can be found in the HTA’s code of practice on consent (refer to useful links and resources on page 49).

28. While the HTA must take into account the report from the IA in its decision making of living donation cases, the Authority is free to seek appropriate additional information from the donor and / or the recipient or 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 Authority 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) [HT Act s38(2)].

29. In reaching a decision about whether it is “satisfied” in relation to the tests described at paragraph nine, the Authority has taken legal advice that “satisfied” is to mean satisfied on the balance of probabilities when considering the tests in their entirety. For each individual test, the Authority will consider whether it has sufficient evidence to be satisfied. In situations where it is not satisfied, the Authority will provide its reasoning as part of its notice of decision set out in the Regulations 11(5).

30. The Authority interprets “duress or coercion” to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.

31. 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”.

32. Further guidance on the interpretation of duress and coercion and reward are provided in the section of this document describing the IA interview.
33. In assessing whether removal for transplantation is “otherwise lawful”, the Authority 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 Authority is presented with evidence that the removal is unlawful.

**Living donation concepts and definitions**

34. 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 a social networking website - bringing the donor and recipient together for the purpose of transplantation. For examples of directed altruistic donations please see the table on pages 12 - 14.

**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 and pooled donation** - A form of donation where a healthy donor is unable to (or chooses not to) donate because they are either incompatible with their recipient, or prefer a better match. They may be matched with another donor and recipient in the same situation in the National Living Donor Kidney Sharing Schemes. The donor organs are then swapped. When two pairs are involved it is a paired donation and where more than two pairs are involved it is a pooled donation [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** - 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 organ removed may prove suitable for transplant into another person (e.g. a kidney removed as part of a person’s treatment). *The HTA does not regulate domino donations.* This is because, although it is a living donation, the donation arises from the patient’s treatment.

35. 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

36. 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.

37. If the donor and recipient have a genetic relationship which is not included on this 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 HTA LDAT and can be assessed by any IA. If such evidence cannot be provided then the case will be designated as a directed altruistic donation and must be referred to an enhanced IA and will be assessed either by the LDAT or by an HTA panel depending on the circumstances of the case.

38. The table below provides information on the different types of cases, whether an enhanced IA must carry out the assessment and the type of HTA approval that will be given.
<table>
<thead>
<tr>
<th>Type of case</th>
<th>HTA definition</th>
<th>Who can complete the independent assessment?</th>
<th>Type of decision?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASES THAT ARE CONSIDERED BY THE HTA LIVING DONATION ASSESSMENT TEAM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directed kidney / liver donation between donor and recipient who are in a qualifying relationship</td>
<td>There is a genetic and/or established emotional relationship between donor and recipient.</td>
<td>Any IA</td>
<td>A member of the HTA Living Donation Assessment Team will access these cases for decision</td>
</tr>
<tr>
<td>Directed kidney / liver donation between donor and recipient who are in a non-qualifying genetic relationship</td>
<td>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 cousins for example, then the case would be considered as a directed altruistic donation case. Example: Cousin</td>
<td>Any IA</td>
<td>A member of the HTA Living Donation Assessment Team will consider these cases for decision</td>
</tr>
<tr>
<td>Directed kidney / liver donation between donor and recipient who are in other forms of pre-existing relationship</td>
<td>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</td>
<td>Any IA</td>
<td>A member of the HTA Living Donation Assessment Team will consider these cases for decision</td>
</tr>
<tr>
<td>Directed altruistic cases – domestic donor Non-qualifying genetic relationship and no pre-existing emotional relationship</td>
<td>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:</td>
<td>IA who has completed enhanced training</td>
<td>A member of the HTA Living Donation Assessment Team will consider these cases for decision</td>
</tr>
<tr>
<td>Type of case</td>
<td>HTA definition</td>
<td>Who can complete the independent assessment?</td>
<td>Type of decision?</td>
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</tr>
<tr>
<td><strong>CASES THAT ARE CONSIDERED BY A PANEL OF THREE HTA AUTHORITY MEMBERS DUE TO THE ASSOCIATED REGULATORY RISKS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Directed altruistic cases – overseas donor | Donor and recipient have a non-qualifying genetic relationship and have no established emotional relationship and the donor is travelling from overseas.  
Donor and recipient have neither a genetic relationship nor a pre-existing emotional relationship and the donor is 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. | IA who has completed enhanced training                                                                                                         | An Authority panel will consider these cases for decision                         |
| Directed donation cases where the 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 |                                                                                                                                                                                                          | IA who has completed                                                                     | An Authority panel will consider these cases for decision                         |
| relationship has an economic dependence | 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 to some cases. Please contact the HTA Living Donation Assessment Team for further guidance on specific cases. Examples: The donor is an employee of the recipient or an employee of a friend of the recipient. The concerns here could be that the donor may seek a reward for the donation (either monetary or maybe a promotion at work). Also, that 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 (living rent free for a period of time). Also, that the recipient may coerce the donor to proceed by suggesting the use of the property is dependent on the donation. | enhanced training | cases for decision |
| 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. | Any IA | An Authority panel will consider these cases for decision |
| Paired and pooled donation cases | Donor wishes to donate to an identified person, but is unable to or chooses not to do so 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 National Living Donor Kidney Sharing Schemes. The donated organs are effectively swapped and each recipient in the pair or pool is transplanted. | Any IA | An Authority panel will consider these cases for decision |
Independent Assessors (IAs)

39. The HTA’s role in living organ donation is to ensure that 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: ensuring each individual donor has an opportunity to speak freely to someone not connected with the transplant unit in order to confirm that their wish to donate is free from any pressure to act against their will. 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.

40. 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 renal units.

41. IAs will have different working relationships with the clinical teams; some have close working relationships and some do not have close contact with the clinical teams at all. Regardless of the relationship, it is 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.

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

The IA role

43. 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 compulsory 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.

44. All IAs receive initial training from the HTA, and this allows them to conduct interviews for the majority of cases (those which are marked as “Any IA” in the table on pages 12 - 14). Some IAs will have also received enhanced training from the HTA, which is a separate session from the initial training. Those IAs who have received this training are able to conduct interviews for any type of case, and are the only IAs able to do this in cases of directed altruistic
donation and cases where there is an economic dependency between donor and recipient.

45. 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.

46. The referral letter should contain all the necessary information for comprehensive donor and recipient interviews to be carried out. The HTA does not believe it is necessary for IAs to have access to the donor or recipient’s medical notes to fulfil the statutory requirements of the IA interview.

Resources required for the role

47. The resources required by IAs to carry out their roles should be provided by the hospital trust.

48. 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 renal unit for translating services if required;
- access to networked IT equipment;
- somewhere secure to temporarily store notes from interviews, for example a lockable filing cabinet.

49. IAs conduct this legally required activity on a voluntary basis without resource allocation from the HTA.

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

51. The HTA is not funded to remunerate IAs and policies on IA remuneration differ between hospital trusts. Any queries should be dealt with by the hospital trust.

Person specification

52. Before contacting a Living Donor Coordinator, 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 patients and exploring and addressing health issues and health risks;
• familiar with requirements to maintain patient confidentiality;
• the ability to work confidently in a hospital environment;
• experience of report writing to a high standard;
• familiar with equality and diversity legislation.

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

Current IAs include:
• Consultants from a variety of specialist backgrounds;
• professionals allied to medicine;
• hospital Chaplains;
• retired healthcare staff including GPs, senior nurses and surgeons.

53. If an individual is interested in applying to become an IA, but unsure whether they meet the requirements above, they should contact their local Living Donor Coordinator in the first instance. Contact details for Living Donor Coordinators are available on the HTA website (see useful links and resources on page 49).

54. Enhanced IAs are those that have received additional training from the HTA.

Training and Accreditation

55. In order to be accredited, an individual must complete an application form, including details of a referee to support their application (usually their Head of Department or Manager), and submit it to the LDAT, via a Living Donor Coordinator. The HTA will only accept applications from people where a Living Donor Coordinator has confirmed there is a 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 event.

57. Following successful completion of the training, a certificate of accreditation will be issued and a letter of confirmation sent to the individual. A letter will also be sent to the Chief Executive of the Trust and the Clinical Director at the unit, in addition to the Living Donor Coordinator. This letter will confirm the IA’s accreditation.
58. It is recommended that once accredited, IAs observe an IA interview with an experienced IA.

**Enhanced IA training**

59. Directed altruistic donation cases have additional complexities which stem from the fact that third parties (for example, friends or the media) will have been involved in bringing a donor and recipient together for the purposes of organ donation. The third party may have been actively involved (for example a brokerage website), or passively involved (for example, a general social media website).

60. Due to the added complexity of these cases it may be more difficult to ascertain that the legal requirements are satisfied. The HTA offers enhanced training for IAs and only those IAs who have completed this training will be qualified to interview donors and recipients in directed altruistic donation cases.

**Reaccreditation and performance assessment**

61. IAs are reaccredited on an annual basis. The process consists of:

- a quantitative assessment (i.e. assessment of the number of reports an IA has completed in a calendar year);
- a performance assessment (i.e. an assessment of the quality of an IAs reports and their wider performance throughout the year);

62. The assessment covers all reports that have been received from each IA between 1 December and 30 November (12 month period).

63. The outcome of the assessment determines whether the IA is automatically reaccredited or will need to complete a short refresher package. Where refresher training is required this will consist of completing a package designed to remind IAs of HTA reporting requirements and the level of detail required.

64. If an IA:

- meets all the criteria, they will automatically be reaccredited;
- does not meet either the quantitative criteria or performance assessment criteria, they will be asked to complete a short refresher package;
• does not successfully complete the refresher package, they are informed that in order to regain accreditation they will need to attend an IA training day.

65. The HTA requires IAs to behave in a professional manner at all times. Complaints regarding IAs will be dealt with in line with the appropriate HTA procedure.

66. Further information on the reaccreditation and performance assessment process is available on the HTA website (see useful links and resources on page 49).

**Liability of Independent Assessors**

67. 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**

68. The Authority has a legal obligation to assess all cases that are referred to it. 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 Authority 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 to the LDAT.

69. Panel cases by law comprise situations where:

• the donor is a child
• the donor is an adult lacking capacity to consent
• paired donations
• pooled donations
• non-directed altruistic donations
70. Retained panel cases are further divided into three sub-categories:

- **Certain directed altruistic donation cases**: 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) bringing the donor and recipient together for the purpose of transplantation). Of these cases, the Authority retains decision making in situations where the donor is travelling from overseas.

- **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.

71. A member of the LDAT may consider that a case, if it is novel or complex, requires further scrutiny. In those circumstances the case will be referred to an Authority panel.

72. A table providing information on all types of cases and the HTA requirements associated to these can be found on pages 12 - 14.

**Responsibilities of Clinicians and Transplant Teams**

73. The HTA recognises that particular living donation cases, or classes of case, 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 practitioners concerned.

74. While the HTA provides advice on how our regulatory requirements will apply to individual cases, the decision on whether to work up a case rests with the unit. 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 for units to use to ensure that all the legislative requirements are addressed in the referral letter to the HTA.

75. The HTA recommends that all potential donors should be provided with a copy of the HTA Information about living donor transplants leaflet at an early stage in the work-up process. Copies of this leaflet can be requested from the LDAT, and are available to download in a range of languages from the HTA website.

76. 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. Some of these are detailed in the useful links and resources section on page 49.

77. The law requires that the HTA makes an assessment of any living organ donation application 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 from the unit. The following sections will note the legal requirements and which are policy matters.

**Halted work-up**

78. There are, on occasion, cases which are halted during the work-up process, and units take the decision not to proceed with a particular donor and recipient pair. These cases do not reach the stage of Independent Assessment. Some of these are halted for clinical reasons, but others are halted for other reasons.

79. Currently there are no national data collected on the reasons for halted work-ups. Working with the National Crime Agency, the HTA believes there is a duty on clinicians to fill this gap where the halted work-up is a result of an indication of organ trafficking and people trafficking for the purposes of organ donation.

80. Specifically, the HTA must be informed about halted 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.

81. It is important to bear in mind that, whether or not a case reaches the HTA for assessment, criminal offences either under the Human Tissue Act, or people trafficking legislation may have been committed.

Prevention of trafficking - both of human beings and of organs

82. The Council of Europe convention to combat trafficking in human organs defines trafficking as:

   o Illicit removal of organs:
     • Removal without the free, informed and specific consent of the living donor
     • Where, 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 advantage
   o Use of illicitly removed organs for the purpose of implantation or other purposes
   o Illicit solicitation or recruitment (of organ donors or recipients), offering or requesting of undue advantages (to/by health professionals or public officials)
   o Preparation, preservation, storage, transportation, transfer, receipt, import or export of illicitly removed human organs
   o Aiding or abetting and attempt

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

   o Action – Recruitment, transportation, transfer, harbouring or receipt of persons.
   o Means – Threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person.
   o Purpose – Removal of organs.

84. The following 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 they are bonded by debt, or in a situation of dependence?

85. 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.

86. 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**

87. 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.

88. If a donor lacks the capacity to consent it is recommended that contact is made with the HTA early on during the work-up in order that specific advice can be provided. It is also recommended that advice is sought from the hospital trust’s legal team.

89. It is important that the donor understands that they will need to provide consent to both the surgical procedure under common law, and the use of the organ for the purpose of transplantation under the HT Act.

90. To ensure that informed consent of the donor is gained, for both common law and the HT Act, the transplant team should make sure the following areas are fully discussed with the donor:
• The nature of the surgical / medical procedure and medical treatments involved for the donor, and the short and long term risks (this should be explained by a medical practitioner with appropriate qualifications to give this information). This information should include the risk of death to the donor.
• The chances of the transplant being successful and any possible side-effects or complications for both donor and recipient.
• The right to withdraw consent at any time before the removal of the transplantable material.
• The decision to donate must be free of duress or coercion.
• That it is an offence to give or receive a reward for the supply of, or for an offer to supply, any 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.

91. 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 on page 49).

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

93. In addition to the information above, there may be further information specific to that donor and / or recipient which the transplant team consider the donor must be told about in order to make an informed decision.

94. 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.

95. The donor should also be given a copy of the HTA Guidance for living organ donors on the HTA independent assessment process and the donor declaration form (see useful links and resources on page 49) 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.

Absence of a previously presumed genetic relationship

96. The HTA has previously been asked, in cases in which a presumed genetic relationship is not substantiated by test results, whether the donor must be informed of this in order to meet the HTA requirements that sufficient information is given to reach an informed decision on whether to continue to consent to donate.

97. 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 on page 49). The *UK Guidelines for Living Donor Kidney Transplantation* recommends that this matter is also explored with the recipient. However as this aspect is outside the HTA’s remit the approach to be taken should be decided at a local level.

98. The decision as to whether to proceed with a living donation when evidence that a presumed genetic relationship does not exist is found is for the relevant transplant team to make. This, in the experience of the HTA, is likely to require involvement from the hospital trust’s legal team.

Proof of identity

99. Written referrals must include confirmation that the Living Donor Coordinator 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.

100. 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

101. The following guidance is not applicable in cases of non-directed altruistic donation.
102. Evidence of relationship should be brought to the IA interview and confirmed in discussion with the IA.

103. In Scotland it is a statutory requirement in cases of directed donation that donor and recipient prove the relationship is as stated by each of them.

104. If the donor and recipient claim a relationship but are not able to provide any documentary evidence we advise the Living Donor Coordinator to contact the HTA for advice.

105. 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.

106. 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 questions them both on the background of their relationship. The HTA will use 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**

107. For genetically related individuals, birth certificates of donor and recipient and of other relatives where necessary to establish the genetic connection, should be provided in order to verify the stated relationship. Where birth certificates are not available alternative evidence could include:

- 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.

108. For emotionally related individuals, examples of documentary evidence include:

- 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 similar will be considered
• an affidavit attesting to the relationship

**Directed altruistic cases – evidence**

109. In order to identify whether a case fits the criteria of a directed altruistic donation case, and must therefore be referred to an enhanced IA, the transplant team should explore the nature of the relationship between the donor and recipient and how the offer of donations arose and confirm this in the referral letter. In England, Wales and Northern Ireland, this requirement is for administrative purposes in order to determine which IA should assess the case and the process for consideration by the HTA.

110. Evidence of the relationship should be provided where possible, for example in the case of cousins without an emotional relationship, however there will be no evidence in most cases of directed altruistic donation as by its very nature it is not likely the donor and recipient had a relationship prior to the offer of donation arising.

**Donor declaration form**

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

112. All donors are asked to provide a signed declaration confirming there is no reward associated with 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 to submit it to the HTA (see useful links and resources on page 49).

**Organs or part organs that cannot be transplanted**

113. The following guidance is not applicable in cases of non-directed altruistic donation and therefore these donors do not need to be asked.
114. All donors should be asked during work up what they wish to happen in the event that their organ cannot be transplanted into the intended recipient. This is a precaution to avoid the possible worst case scenario of an organ being disposed of when the donor’s wishes are not known. The HTA has identified four potential options:

- Organ or part organ can be transplanted into an alternative recipient (this will be someone on the national waiting list for a kidney donation); if the donor’s preference is for an identified alternative recipient, for example if another family member or friend requires a transplant and the donor is a suitable match, an additional set of directed donation IA interviews must be submitted;
- 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.

115. The HTA must give separate approval 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 on page 49).

**Joint interviews**

116. 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.

117. In these cases the transplant team should contact the LDAT to make an application for the requirement for the joint interview to be withdrawn. These applications will be considered by the Director of Strategy and Quality.

**Translators**

118. 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 the IA is aware a translator will be required for their interview. It is acceptable for telephone translators to be used. Form HTA IT (DC) should also be completed and accompany the referral letter (see useful links and resources on page 49). Please note that the HTA IT (DC) form does not need to be sent to the HTA.
119. 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.

120. In no circumstances should a translator be used who is known to the either 
the donor or recipient.

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

**Referral letter**

122. The Regulations require that a medical practitioner with clinical responsibility 
for the donor must have caused the matter to be referred to the Authority. 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; and has
- Provided the donor with the information the donor requires to understand 
the consequences of donation;
- Endeavoured to obtain information from the donor that is relevant to 
transplantation.

123. 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. A model referral letter is available; please refer to the 
useful links and resources on page 49.

**The referral process**

124. The referral should be made by a registered medical practitioner, or a person 
acting under their supervision. The HTA considers a Living Donor Coordinator 
to be a suitable person to make the referral.
125. The referral is made to the HTA at the point at which it is received by the IA. It is important that in cases of directed altruistic donation that the referral is made to an IA who has received enhanced training. A list of these IAs is available from the LDAT. The IA will then provide the HTA with a copy of the referral letter. The preference of the HTA is that the referral letter will be scanned and sent with the IA report electronically to the HTA. However, this may not be feasible for all IAs and prepaid envelopes are available on request.

Other considerations

126. 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.

127. 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 hour’s service

128. If a rapid assessment is needed out of hours then the NHSBT Duty Office should be contacted on 0117 975 75 75.

129. The NHSBT Duty Office will contact the on-call HTA representative, who will in turn contact the relevant transplant unit. The transplant unit will be required to organise the IA interviews at short notice. The HTA representative will then assess the case and issue approval if the legal requirements are met.

130. Out of hours cases are rare and have historically been 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.

131. 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. The IA will need to complete an electronic report at the first available opportunity (normally the following morning).
Responsibilities of Independent Assessors

General requirements

132. 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 an interview must be undertaken with donor and recipient together. The purpose of this is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor’s decision to donate and to explore the issue of reward jointly with the donor and recipient.

133. 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.

134. 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 Authority’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 on pages 39 – 44.

Requirements for Authority panel cases

135. Some panel cases require increased scrutiny and for independent assessments to be completed by an IA who has completed enhanced training, for example for directed altruistic donation cases. Information on which types of cases can only be assessed by enhanced IAs can be found in the table on pages 12 - 14. IAs must ensure that they are only allocated cases which they have the necessary training to assess.

Accepting referrals

136. 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 in the five working days following the submission of their report, in case the LDAT needs to contact them for further information or clarification.

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

The Independent Assessor interview process

Interviewing donors and recipients

138. 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 report of the interviews.

139. 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 and 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.

140. 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.

141. While the donor and 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 where the donor is alone with the IA to provide the
opportunity for the donor to confirm that their consent is being freely given without any outside influence being able to affect their response.

142. If the recipient is a child then 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.

143. 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.

144. It is not necessary for an IA to have Disclosure and Barring Service (DBS) checks in order to interview a child where there is another adult in the room. Hospital trusts may have different policy requirements and we would advise Living Donor Coordinators to seek further information on these from their trust’s legal team.

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

146. 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 reschedule.

147. 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 call for IAs in 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.

148. 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 under section D
149. The HTA advises that IA interviews should not be recorded for broadcast. If this matter arises please contact the LDAT for advice.

**Interview content – donor and recipient**

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

150. 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.

151. 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**

152. 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.

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

154. 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.

155. 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.
156. 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 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.

157. 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.

158. 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.

159. 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.

160. The reimbursement of reasonable expenses incurred as a direct result of living kidney donation in England will be made directly by NHS England (other 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.

161. It is acceptable for a recipient (or the family of the recipient) to directly reimburse the donor if circumstances necessitate this. In this circumstance the donor and recipient must to be able to provide evidence in order to prove that only direct travel costs were paid for, and the donor has not materially benefitted in any way.

162. Further information on the reimbursement of living donor expenses can be found in the UK Guidelines for Living Donor Kidney Transplantation (see useful links and resources on page 49).

163. As referenced at paragraphs 110-111 the donor is required to sign a declaration confirming there is no reward. A copy of the declaration form is available from the useful links and resources on page 49.

*Any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome*
164. The translator used should have no personal connection with either the donor or the recipient; should have some understanding of medical matters, and should speak the donor’s and recipient’s language fluently.

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

166. IAs can also act as translators provided that they are fluent in the specified language.

**Interview content – donor only**

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

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

168. The donor may state to 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.

169. 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.
170. In addition, the Regulations (Scotland) require that the report from the donor interview also covers any relevant wider implications arising from the intended donation, including the effect on any children or dependent relatives of the donor.

**Interview content – recipient only**

171. 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.

172. The Regulations (Scotland) require the recipient interview (in cases of directed donation) report on ‘any duress or coercion affecting the decision of the recipient to be a recipient of the organ or part organ in question’.

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

174. 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. Below are the exceptions to this:

- Where the recipient unarguably lacks capacity, for example if they are a baby, then attempting an interview would be disproportionate and result in unnecessary use of resources. Similarly, there may be 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.

175. 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.

176. 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.

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

Interviews with person giving consent if different from the donor

178. The Regulations require that where a donor is unable to give consent, the case must be assessed by a panel of Authority Members and the IA must interview a person who is consenting on the donor’s behalf. Information on the capacity of the donor will be included in the referral letter and it is recommended that when it is indicated that the donor does not have capacity that contact is made with the LDAT.

Other requirements for the IA report

179. 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.

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

- Ensure the donor and partner are fully aware of the process involved and that they are aware of the specific implications; for example, if one kidney is not able to be removed or be transplanted. More information can be found in the NHSBT leaflet National Living Donor Kidney Sharing Schemes (see useful links and resources on page 49).

181. In cases of non-directed altruistic donation the following additional points should be explored:

- Ensure the donor is aware of the meaning of non-directed organ donation, in the sense that they will not have a say in who receives the organ and
that they may never know the recipient’s identity. More information can be found in the NHSBT leaflet *National Living Donor Kidney Sharing Schemes* (see useful links and resources on page 49).

**Completing and submitting the interview report**

182. 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 transplant team and the HTA.

183. 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 to the report also (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 on page 49).

184. 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.

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

<table>
<thead>
<tr>
<th>Report section</th>
<th>Mandatory information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A – Category of transplant</td>
<td>In this section, IAs are asked to confirm that they have read, understood and applied the guidance issued by the HTA.</td>
</tr>
<tr>
<td></td>
<td>IAs are asked to confirm if the transplant will be taking place in Scotland. If yes, please indicate this in the report to ensure you see the relevant report sections for Scotland.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Section B – Details of donor, recipient (or partner) and location of transplant</td>
<td>Details on the donor, recipient (or partner) and units must be entered here. 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.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Section C – Evidence of identity and status of relationship</td>
<td>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.</td>
</tr>
<tr>
<td>Section D – About the donor</td>
<td>In this section, IAs are asked to confirm whether: <em>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?</em> The IA must confirm that the donor is either: <em>An adult with capacity to understand the donation process in order to consent or; A child who is competent to understand</em></td>
</tr>
</tbody>
</table>
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.

In Scotland this must also include information that the donor has considered the wider implications, including the effect on any children or dependent relatives.

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.
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.

<table>
<thead>
<tr>
<th>Section G – In directed cases, section G is on duress, coercion and reward</th>
</tr>
</thead>
<tbody>
<tr>
<td>For directed cases, section G is on duress, coercion and reward.</td>
</tr>
<tr>
<td>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:</td>
</tr>
<tr>
<td>• There was no evidence of duress or coercion affecting the donor’s decision to give consent (in Scotland this must also confirm there was no evidence of duress or coercion affecting the decision of the recipient to be a recipient of the organ in question);</td>
</tr>
<tr>
<td>• There was no evidence of an offer of a reward that would affect the donor’s ability to give consent.</td>
</tr>
<tr>
<td>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. 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 no reward has been or is to be given and that there is no duress or coercion</td>
</tr>
<tr>
<td>IAs must also confirm if they have received a signed donor declaration or</td>
</tr>
</tbody>
</table>
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.

**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.

<table>
<thead>
<tr>
<th>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:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- There was no evidence of duress or coercion affecting the donor’s decision to give consent; (in Scotland this must also confirm there was no evidence of duress or coercion affecting the decision of the recipient to be a recipient of the organ in question);</td>
</tr>
<tr>
<td>- There was no evidence of an offer of a reward that would affect the donor’s ability to give consent.</td>
</tr>
</tbody>
</table>

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.

186. A copy of the referral letter and donor declaration should be submitted at the time of the report submission, ideally by scanning and uploading the two documents alongside the IA report. For those without document scanning facilities, please forward copies of the referral letter and signed donor declaration immediately after the interviews in the prepaid envelope provided.
by the HTA. These envelopes are available on request via transplants@hta.gov.uk.

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

188. Once a decision has been made by the HTA, an automated notification will be issued to the IA, and the Living Donor Coordinator(s) and Clinicians detailed in the report. The decision can be accessed by logging into the portal. The HTA recommends that more than one Living Donor Coordinator 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.

189. There is no time limit on the validity of an approval. This is in contrast to the previous six month time limit which was applied. However, if the circumstances of the donor and/or recipient change during the time between approval being granted and the transplant going ahead, 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**

190. 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. The case will then be considered for decision.

191. 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**

192. 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. If information is unclear or is missing from the report, the IA will be contacted for further clarification.

193. A panel will be convened and the case will then be considered for approval.
194. If a panel of three Authority Members cannot reach a unanimous decision, the panel may reach a majority decision.

195. 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**

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

(i) there are questions about the donor’s capacity to consent
(ii) there are indications that the donor is being coerced or is under duress
(iii) there is any indication that reward has been offered, given, sought or received
(iv) IA comments indicate any unease with the application

197. 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.

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

- further discussions with the Living Donor Coordinator or the IA;
- the decision to undertake a further directed IA interview with the donor, the recipient or both (it may be necessary to use an enhanced IA);
- the decision to interview the donor, the recipient or both directly;
- a request for further supporting documentation.

**Regulatory Decision Meeting**

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

200. 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.

201. Where there is insufficient evidence for the Authority to be satisfied that the donor has capacity to consent, the Authority may refer the case back to the medical practitioner, who will be asked to provide the evidence underpinning their assessment described at paragraph 123.

Service Standards

202. 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 it needs to assess the case.

203. 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.

204. 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

205. 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)

206. 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.
207. In deciding to reconsider a decision the Authority 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.

208. 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.

209. 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;
- The registered medical practitioner who caused the matter to be referred to the HTA

**Contingency report system**

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

- if the system cannot be accessed online, 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 IA page of the HTA website.

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

212. If a report cannot be received or submitted by email, a copy should be sent to fax number 020 7269 1999, it is key that the HTA is contacted before the fax is sent to confirm that this can be securely received.
## Useful links and resources

**Human Tissue Authority resources**

| Leaflets | Information about living donor transplants  
http://www.hta.gov.uk/publications/leaflets.cfm |
| --- | --- |
| Guidance | Guidance for living organ donors on the HTA independent assessment process  
http://www.hta.gov.uk/publications/leaflets.cfm  
Guidance for using the portal  
http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm  
IA reaccreditation and performance assessment process  
http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm  
Code of practice 1 – Consent  
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm  
Code of practice 2 – Donation of solid organs for transplantation  
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm  
Organs Intended for Transplantation – documentary framework  
http://www.hta.gov.uk/organdonationdirective/legislationonor gandonationdirective.cfm  
Licensing on organ donation directive  
http://www.hta.gov.uk/organdonationdirective/licensingonorg andonationdirective.cfm |
| Policy or position statements | Position statement on absence of a presumed genetic relationship  
Policy on an organ that cannot be transplanted into the intended recipient  
http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/organ/partorganthatcannotbetransplantedintotheintendedreci pient.cfm |
### Forms

- **Independent Assessor application form**  
  [http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm](http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm)

- **Donor declaration form**  

- **Form HTA IT (IA)**  
  [http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm](http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm)

- **Form HTA IT (DC)**  
  [http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm](http://www.hta.gov.uk/bodyorganandtissuedonation/organdonations/independentassessors.cfm)

### Contacts

- **Contact details for transplant units and Living Donor Coordinators**  

### External resources

#### Leaflets

- **NHS Blood and Transplant**

  - **National Living Donor Kidney Sharing Schemes**  

  - **Could I be a living kidney donor?**  

  - **Living donation – medical information**  

#### Guidance

- **British Transplantation Society**

  - **UK Guidelines for Living Donor Kidney Transplantation**  
| Council of Europe |
| Convention on Action against Trafficking in Human Beings |
| Home Office – Visitor Guidance |

| 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 |
| The Quality and Safety of Organs Intended for Transplantation Regulations 2012 |
| http://www.legislation.gov.uk/uksi/2012/1501/contents/made |
| Mental Capacity Act 2005 |
| Mental Capacity Act code of practice 2005 |
| http://www3.imperial.ac.uk/pls/portallive/docs/1/51771696.PDF |
| Human Tissue (Scotland) Act 2006 |
| The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 |
| Human Rights Act 1998 |

| Charities and sources of information |
| The following resources may be useful for potential donors: |
| Living Kidney Donation |
| http://livingkidneydonation.co.uk/ |
| Give a Kidney – one’s enough |
| http://www.giveakidney.org |
Living Donor Coordinator quick reference process flowchart

The transplant unit must make a decision on what case category the donation comes under and what IA should carry out the assessment.

According to BTS Table 5.2.1 referral to the HTA should occur after the final pre-operative discussion with Consultant Nephrologist and Transplant Surgeon. This is 2-3 weeks from beginning your investigations.

Date identified with D+R and suitable IA for HTA Independent Assessment

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.

Donor must receive the document Guidance for living organ donors on the HTA Independent Assessment process and a blank donor declaration form.

Use HTA model referral letter template

Gather all information required for the referral letter
Some of the information is mandatory
Referral letter should be sent in advance of the IA interview to allow the IA sufficient time to prepare.
Referral letter received and checked by IA

IA must check case type. If the case requires an enhanced IA, have you completed the enhanced training?

If they do not have this:
Check if Living Donor Coordinator sent them a copy of the Guidance for living organ donors on the HTA Independent Assessment process and donor declaration form

Offer them a copy of guidance to read and ask the donor to sign the declaration before their interview

If they refuse to sign the donor declaration, please proceed with the interview and explore their reasons for not wanting to sign. A summary of the conversation should be noted in your IA report.

At beginning of IA interview
Check identification of D+R and evidence of the relationship (where applicable)

Ask donor for the signed copy of the donor declaration

If they do not have this:
Check if Living Donor Coordinator sent them a copy of the Guidance for living organ donors on the HTA Independent Assessment process and donor declaration form

Offer them a copy of guidance to read and ask the donor to sign the declaration before their interview

If they refuse to sign the donor declaration, please proceed with the interview and explore their reasons for not wanting to sign. A summary of the conversation should be noted in your IA report.

IA interview carried out

Interview:
- Donor
- Recipient
Donor and recipient together

Complete online HTA report

Refer to relevant HTA guidance documentation

Provide HTA with copies of the referral letter and signed donor declaration

Scan and upload documents with HTA report
or
Send via prepaid envelope within 7 days of the IA interview

Submit report to HTA

HTA notification sent to confirm report has been received

Case reviewed by HTA Living Donation Assessment Team and assigned for consideration
Cases are considered either by the HTA Living Donation Assessment Team or by a Panel of three Authority Members

Notification of decision sent by HTA
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.
- Have I included whether the donor confirmed they understand that there is a risk of death occurring?
- Have I included other specific risks that the donor mentioned?

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 is able to liaise with the transplant coordinators.

EXAMPLE ANSWER FOR KIDNEY

*The donor has a clear understanding of the proposed surgery to remove her kidney. Unprompted 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 or chest*
infection is 2% and the risk of death 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. Said 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. In Scotland it
is important to also ask the recipient whether they feel under pressure to receive the organ.

- 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 paras 150-161 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.
For more information about us please visit www.hta.gov.uk or contact:

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www.facebook.com/HumanTissueAuthority

Published in March 2015