



Guidance for transplant teams and Independent Assessors

Living donor transplantation

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Introduction

1. This document is intended to provide guidance to Independent Assessors (IAs), clinicians and transplant teams about the regulatory requirements for the assessment and approval of prospective living organ donations by the Human Tissue Authority (HTA).
2. This guidance should be read in conjunction with the HTA's code of practice on the Donation of solid organs for transplantation, and the code of practice on Consent. Both codes can be found on the HTA's website at www.hta.gov.uk.
3. Separate guidance is available on the regulatory requirements for the assessment and approval of allogeneic bone marrow and peripheral blood stem cell donations for transplantation. Practitioners working in this area should also refer to the code of practice on the Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation. Again both documents can be found on the HTA's website.

The regulatory framework

The Human Tissue Act 2004

4. The Human Tissue Act 2004 (the Act) sets out the legal framework for the storage and use of human organs and tissue from the living and for the removal, storage and use of human organs and tissue from the deceased. The Act covers England, Wales and Northern Ireland.
5. The 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 persons. The Act governs consent for the **storage** and **use** of organs or part organs taken from a living person for the purpose of transplantation.

Scottish legislation

6. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA performs certain tasks on behalf of the Scottish Government. Scottish law covering living organ donation is broadly similar to the law in the rest of the UK, although there are some significant differences, particularly in respect of adults lacking capacity and children. Scottish Ministers have asked the HTA to regulate donation approvals on their behalf.
7. More information on requirements in Scotland can be found at appendix B.

The Human Tissue Authority

8. The Act established the HTA to regulate activities concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos) for Scheduled Purposes set out in the Act, including for the purpose of transplantation.
9. One of the HTA's statutory functions is to issue codes of practice. These Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit and lay down the standards expected. The 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
 9. Research
10. The HTA is also a Competent Authority in the UK under The Human Tissue (Quality and Safety for Human Application) Regulations 2007, which implement the European Union Tissue and Cells Directives. These cover the whole of the UK, including Scotland.

Overview of the regulatory framework for living donation

11. The requirements for living donor transplantation are set out in the Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations).
12. The Act requires that, with the exception of domino donations, all living organ donations for transplantation must be approved by the HTA before the donation can take place. The HTA fulfils this duty through an independent assessment process.
13. Before the HTA can approve such cases, it must be satisfied that:
 - no reward has been, or is to be, given to the donor (see 55–59 for further information)
 - consent to removal for the purpose of transplantation has been given by the donor (or removal for that purpose is otherwise lawful, e.g. where court approval for the removal has been obtained)
 - an Independent Assessor has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient (and / or the person acting on behalf of the recipient) and submitted a report of their assessment to the HTA

Additionally, in cases of directed genetically or emotionally related donation, the HTA requires evidence of relationship be provided to establish that the relationship between donor and recipient is as stated.

14. Further guidance and information on the regulatory framework is available in the HTA's code of practice on the Donation of solid organs for transplantation, available from the HTA's website: www.hta.gov.uk.

Consent

15. The requirements of the Act are intended to ensure 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. Further details are available in the special considerations section of the code of practice on the Donation of solid organs for transplantation available on the HTA website: www.hta.gov.uk.
16. Guidance on consent under the Act can be found in the HTA's code of practice on Consent, available from the HTA's website: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm>.

Types of living donation

17. The Act and Regulations allow a number of different forms of living donation within the UK, which all require assessment by an IA, and HTA approval. These are:
 - Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired/pooled donation). Forms of directed donation are:
 - genetically related donation: where the potential donor is a blood relative of the potential recipient
 - emotionally related donation: where the potential donor has a relationship with the potential recipient; for example, spouse, partner, or close friend
 - paired donation: where a relative, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, and they are matched with another donor and

recipient in a similar situation, so that both people in need of a transplant receive a compatible organ

- pooled donation: a form of paired donation whereby the pair are matched with other donors and recipients from a pool of pairs in similar situations, and more than two donors and two recipients are involved in the swap, so that more than two people in need of a transplant receive a compatible organ
- Altruistic non-directed donation: A form of living donation whereby an organ (usually a kidney) or part organ (for example liver or lung lobe) is donated by a healthy person who does not have a relationship with the recipient and is not informed who the recipient will be

Non-directed – domino organ donation

18. Domino donation is a further form of living donation in which an organ or part organ is removed for the primary purpose of a person's medical treatment. The organ(s) removed may prove suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart / lung transplant). The HTA does not regulate domino donations. This is because, although it is a living donation, the donation arises from the patient's treatment. The guidance below is good practice.
19. The prospective donor should agree that the organ to be removed as part of their treatment may be used for someone else. The donor should be informed about the testing for transmissible diseases and the implications of any positive tests.
20. The clinician responsible for the donor should ensure that the donor's consent to the removal of the organ was not obtained by duress, coercion or the offer of any other inducement. The clinician should also be satisfied that there was no evidence of an offer of reward.
21. Once the transplant operation has been performed, the clinician responsible for the recipient should complete an HTA (B) form and send it to NHS Blood and Transplant (NHSBT).

Roles and responsibilities

Roles and responsibilities of Independent Assessors

22. IAs are usually, but not exclusively, based in hospitals with transplant units or referring renal units. Once accredited by the HTA, they act as a representative of both the donor and the HTA, assessing potential living donors to ensure the requirements of the Act have been met.
23. To do this, IAs interview potential donors. They then complete and submit a report to the HTA, detailing whether the requirements have been met. The HTA will then make a decision about a case based on the information provided by the IA.
24. Training will equip all IAs with the skills necessary to conduct a broad variety of assessments. Although some transplant units may have agreements in place with IAs about the type of cases they assess, IAs are expected to assess across the variety of cases referred to them.
25. It is not the role of the IA to determine medical suitability of the donor or recipient. This is the responsibility of relevant 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, and is outside the remit of the HTA.

Resources required for the role

26. Facilities which IAs require in order to carry out their role include:
 - time built into job plan / timetable
 - administrative support and resources
 - a room in which to see the donor and recipient
 - any travel expenses needed to perform their duties as an IA
 - payment by the transplant or renal unit for translating services if required
27. Trusts / hospitals are asked to ensure that IAs are provided with the necessary facilities to carry out their role.

28. Payment for undertaking assessments is something that IAs should agree on an individual basis with their Trusts / hospitals, and is not an issue for the HTA. It should be noted that IAs are not paid by the transplant unit. Their remuneration for the role comes from the NHS Trust / hospital, sometimes on a single sessional basis.

Person specification

29. Before submitting an application to the HTA, individuals interested in becoming an IA should ensure they meet the person specification:
- Current (or recently retired) medical consultant, someone of equivalent registered professional status or a professional working within a hospital environment
 - Registered with a professional body where appropriate, for example, General Medical Council, Nursing & Midwifery Council or equivalent. If retired, maintaining professional registration is not a requirement of the role
 - Independent of the process of human organ transplantation. IAs should not have direct involvement with the transplant programme and / or a vested interest
 - No previous or pending disciplinary action within Trust / hospital or professional body
 - Time available to undertake assessments within the required timeframes (i.e. assessments within one month of referral)
 - Good oral and written communication skills and IT literate
30. IAs come from varied backgrounds. Current IAs include:
- Consultants (and retired Consultants)
 - Senior Sisters / Nurses
 - Hospital Chaplains and Spiritual Care Advisors
31. If an individual is interested in applying to become an IA but unsure whether they meet all the requirements above, they should contact the HTA Transplant Approvals Team for advice (see paragraph 48).

Accreditation

32. Any individual who is interested in becoming an IA and meets the person specification above should contact the HTA Transplant Approvals Team for further information about how to apply.
33. In order to be accredited, an individual must complete a short application form, including details of a referee to support their application (usually their Head of Department or Manager), and submit it to the HTA Transplant Approvals Team.
34. The Transplant Approvals Team will then check the application and request a reference. Once a satisfactory reference has been received, they will contact the individual with log-in details and further information for the e-learning training package, which they must complete to be accredited. Any member of the public may complete the e-learning to learn more about the process. However, only those submitted by individuals who are training to be IAs will be assessed.
35. Following successful completion of the training package, 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 their Trust / hospital with copies sent to the Director of the Transplant Unit or the Clinical Director of the Renal Unit where appropriate, and the living donor coordinator. This letter will confirm the IAs accreditation and the facilities required to undertake the role (as outlined in paragraph 26).

Reaccreditation and performance assessment

36. 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)

The assessment covers all reports that have been received from an IA in that calendar year.

37. The outcome of the assessment determines the way in which IAs achieve reaccreditation. 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 e-learning training package in order to refresh their knowledge of the process. The IA will be reaccredited on completion of this package.
38. Further information on reaccreditation and performance assessment can be found at appendix C.

Liability of Independent Assessors

39. Although the IA acts as a representative of the HTA, the majority are employed by their hospital Trust. Since this work should form part of their NHS commitments, it is expected that any liability will be borne by their Trust / hospital and any claims handled by the National Health Service Litigation Authority. In the case of:
- those who are retired, it is advised for governance purposes that they hold an honorary contract with the Trust/hospital concerned; or
 - those who work as an Independent Assessor in the private sector should ensure they have the appropriate cover
40. It is strongly recommended that both of these categories of IA speak to their defence organisation (Medical Defence Union / Medical Protection Society) who will advise on insurance cover.

Roles and responsibilities of the HTA

41. Under the Act, the HTA has to be satisfied, in all cases of living donor transplantation, that the relevant requirements of the Act (outlined in paragraph 13) have been met. An IA will undertake the assessment and submit a report to the HTA, and the HTA will then make the final decision on each case.
42. There are two levels of decision-making: the first where the HTA Transplant Approvals Team makes the final decision on a case; and the second where a case is assessed by an HTA panel.

Cases which can be approved by the HTA Transplant Approvals Team

43. All straightforward directed donations where the donor and recipient are genetically or emotionally related are assessed by the HTA Transplant Approvals Team.

Cases which must be referred to a HTA panel

44. The following donations must be approved by a panel of HTA members:
- altruistic
 - paired / pooled
 - where the donor is an adult who lacks capacity
 - where the donor is a child aged under 18 years old

In addition, cases involving novel forms of transplantation are referred to panels for assessment. Complex cases, or those where it is not clear if the requirements of the Act have been met, can also be referred to a panel for decision.

45. More information on HTA assessment and approval processes can be found in paragraphs 80–120.

HTA panels

46. HTA panels consist of three Authority members and cannot include non-HTA members. A panel may ask the advice of experts; however, these advisers have no role in approving the donation. Panels are supported by the HTA Transplant Approvals Team.
47. The HTA Transplant Approvals Team acts as the liaison between IAs and panels and will forward cases to a panel where appropriate. Where cases are sent to a panel, the IA may need to supply more information for a final decision to be made (see 94–97). The HTA Transplant Approvals Team will communicate with the IA to request this additional information and relay it to the panel.

Support and guidance

48. The HTA Transplant Approvals Team is available to provide advice and guidance to both IAs and transplant units. The team can be contacted by:

- email: transplants@hta.gov.uk
- phone: Transplants Approvals Team: 020 7211 3447 / 3414
HTA general phone line: 0207 211 3400
- post: Transplant Approvals Team
Human Tissue Authority
Finlaison House
15–17 Furnival Street
London
EC4A 1AB

Roles and responsibilities of clinicians and transplant teams

49. 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 suitable as a living organ donor is a matter for the practitioners concerned, and is outside the remit of the HTA.
50. For living donor **kidney** transplantation, the donor and recipient should be assessed using a protocol based upon British Transplantation Society / Renal Association guidelines (UK Guidelines for Living Donor Kidney Transplantation available at: <http://www.bts.org.uk/transplantation/standards-and-guidelines/>). At present, there are no national guidelines for the assessment of living donors of other organs or part organs.
51. In cases of **non-directed altruistic donation** as well as medical and surgical assessment, psychiatric assessment is a necessary part of the process to ensure fitness to donate ('work up'). It is the responsibility of the transplant team to arrange this. Early psychiatric assessment is recommended to ensure there is no relevant psychiatric or psychological illness.
52. It is recommended that, where applicable, the donor and recipient should be assessed and looked after by different clinicians.

53. Clinicians and transplant teams must also make sure that potential donors are properly informed, and that a written referral is made to an IA, in order to ensure the relevant requirements of the Act are met.
54. Once the transplant operation has been performed, the clinician responsible for the recipient should complete a 'receipt of organ' form (HTA (B) form; see Appendix) and send it to NHSBT.

Informing the donor

55. Potential donors must be provided with sufficient information to reach an informed decision about whether they wish to donate. This information should be provided by the transplant team before the IA assessment.
56. All potential donors should be provided with a copy of the HTA *Information about living donor transplant* leaflet. Copies of this leaflet can be requested from the HTA Transplant Approvals Team, and it is also available to download in different languages from the HTA website.
57. The transplant team should make sure the following areas are discussed in full with the donor:
 - the surgical procedures 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)
 - 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, and the implications of doing so
 - the decision to donate must be free of any kind of coercion or threat against them or anyone else (for example, family or friends); and that a decision seen to be given under such pressure is an offence under the Act
 - it is an offence to seek or receive payment or any other reward for donating organs or part organs for transplantation and that this is an offence under the Act.

Donors are able to seek reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from the donation.

Further details are available in the code of practice on the Donation of solid organs for transplantation available on the HTA website:

<http://www.hta.gov.uk/donations/organdonations.cfm>.

Guidance is also available on the Department of Health website at:

http://www.dh.gov.uk/en/Healthcare/Renal/RenalInformation/DH_4069293

For potential **altruistic non-directed and paired / pooled donors** the following information should also be provided:

- anonymity of the donor and recipient prior to the operations is required, and that confidentiality must be respected
 - how the altruistic, paired / pooled process works, and how a suitable recipient, or in the case of paired/pooled donation, suitable matches, are identified
58. 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 a fully informed decision.
59. The HTA has previously been asked whether, in cases in which a presumed genetic relationship is not substantiated by test results, the donor must be informed of this in order to meet HTA requirements. It is the view of the HTA that for the purposes of directed living donation there must be a genetic **or** emotional relationship between donor and recipient, and that therefore the requirement would still be met in these cases. Whether the donor and / or recipient are informed of test results in such cases is a decision for the clinicians and transplant team who have overall responsibility for their care.

Referring a donor for HTA assessment

60. It is the duty of the clinician responsible for the donor to refer them to an IA for assessment. Referrals must be made in writing. The referral can be written by a living donor coordinator, provided the name of the registered medical practitioner who has explained the procedure and the

risks involved has been specified. See paragraphs 60–79 below for guidance on written referrals.

61. Referrals for IA assessment should be made once ‘work up’ has been completed. This ensures that donors have had the opportunity to be given all the relevant information and discuss it fully with their clinicians and transplant teams prior to IA assessment. Additionally, for practical purposes, if referrals occurred at the beginning of the process, IAs could be required to assess a significant number of cases that do not proceed. Further guidance on the timing and scheduling of referrals and IA assessments can be found in paragraph 79.
62. Transplant teams should also make sure that donors and recipients understand the purpose of the IA assessment and are prepared for the interviews. In particular, they should make sure that necessary documentary evidence of identity and, where applicable, evidence of relationship is provided by donors and recipients. Detailed guidance on evidence requirements is provided in paragraphs 67–76 below.

The referral process

63. Before a transplant involving a living donor takes place, a donor and recipient must receive a full medical assessment to determine whether they are suitable to undergo the procedure. If the donor is deemed suitable, the clinician responsible for the donor must then make a written referral to an IA.

Referral letters

64. Referral letters from donor clinicians (or living donor coordinators) to the IA being asked to undertake an assessment should include the following information:
 - Donor health status – confirmation that the donor is physically and mentally suitable for surgery and that the appropriate clinical investigations have been carried out. In the case of **non-directed altruistic donors** this should include confirmation that a psychiatric assessment has been undertaken; with a copy of the psychiatrist’s report attached.
 - Recipient information – including diagnosis, modality of treatment for organ failure and relevant health history. (This is not applicable in cases of non-directed altruistic donation.)

- Evidence of identity and relationship – relevant documentation to demonstrate identity and the stated relationship of donor and recipient (see paragraphs 67–76 below). (This is not applicable in cases of non-directed altruistic donation.)
- Confirmation that the donor is aware that they can withdraw their consent to the donation of the organ at any time before the operation takes place.
- Confirmation that the benefits and risks have been explained to the donor and recipient including:
 - the procedures involved, both clinical investigations and organ removal
 - the risks of serious surgical complications or even the death of recipient and / or donor
 - the chances of the transplant being successful, including the risks of primary organ failure, long-term rejection and the possibility of recurrence of the primary disease
 - the possible after effects and long-term complications for both donor and recipient
 - the wider implications for the donor’s children and other dependent relatives (e.g. leave arrangements for work, provision made for any required support during recovery period).
- Confirmation that the clinician responsible for the donor is satisfied that the donor’s consent has been given voluntarily (i.e. not obtained by coercion, payment or the offer of any reward).
- Whether the use of an independent translator has been required if so, ensure form HTA IT (DC) (see appendix D) is completed and signed and sent with the referral.
- Email contact details of the clinician responsible for the donor and the living donor coordinator(s) (this is to ensure that both the donor clinician and living donor coordinator(s) can be informed of the HTA’s decision).

65. The referral letter should be sent to the IA with copies of evidence of identity and relationship, and form HTA IT (DC) if a translator has been used. For **non-directed altruistic donors**, a copy of the psychiatric report should be attached to the referral letter.
66. An example of a referral letter from the donor clinician to the IA – HTA RF (DC) – is included in appendix D. This template may be adapted as required for local purposes. Please note that it is not essential to use this template; it is provided as an example only.

Evidence of identity and relationship

67. Written referrals must include confirmation of the evidence seen by the transplant team confirming donors and recipients identities and, if applicable, verifying their stated relationship.
68. Copies of this documentation should be provided with the referral letter, and donors and recipients should also take documentation with them to the IA interview. Original or certified copies of documents should be provided in all cases where possible.
69. Donors should be advised in advance of the documents required. This is particularly important when the donor is from overseas or travelling a long distance to the IA interview.
70. The HTA recognises that obtaining documentary evidence can be difficult in some cases. Should IAs or transplant teams have any questions relating to requirements for documentary evidence, they should contact the HTA Transplant Approvals Team for further advice before the IA interview takes place.

Evidence of identity

71. 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

72. The following guidance is not applicable in cases of non-directed altruistic donation.
73. Documentary evidence is required to verify the stated relationship between donors and recipients. The evidence of relationship required is

different depending on the relationship between donor and recipient. The requirements are listed below; along with examples to demonstrate what forms of evidence should be provided for each type of donation. Original or certified copies of documents should be provided in all cases where possible.

74. Documentary evidence for **genetically related individuals**:

- Long form birth certificates of donor and recipient, and of other relatives where necessary, should be provided in order to verify the stated relationship
- Where birth certificates are not available this should be stated in both the referral to the IA, and the IAs report to the HTA, and alternative evidence should be provided. This alternative evidence could include:
 - family photographs spanning the duration of the relationship
 - certified family tree
 - an affidavit attesting to the relationship
 - statement / testimonial from an individual in a position of authority (e.g. lawyer, teacher, GP) who is able to vouch for the validity of the relationship.

Examples of evidence provided to verify genetic relationship

Brother / sister:

Long form birth certificates of each demonstrating same parentage and photographs spanning the duration of the relationship.

Parent / child (where birth certificates not available):

Photographs spanning the duration of the relationship and statement from family GP supporting the stated relationship.

Cousins:

Long form birth certificates of donor and recipient demonstrating parents' names. Birth certificates of their relevant parents demonstrating their shared parentage.

75. Documentary evidence for **emotionally related individuals**:

- 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
- statement / testimonial from an individual in a position of authority (e.g. lawyer, teacher, GP) who is able to vouch for the validity of the relationship
- an affidavit attesting to the relationship.

Examples of evidence provided to verify emotional relationship

Partners:

Council tax bill for shared address, photographs spanning the duration of the relationship and statement from family GP supporting the stated relationship.

Friends:

Photographs spanning the duration of the relationship, statement from an individual in a position of authority or an affidavit attesting to the relationship.

76. For the purposes of the IA assessment and report to the HTA, particularly in cases where there is limited documentary or photographic evidence of relationship, the IA should ensure that the nature of the relationship and shared history of the donor and recipient are fully explored. The IAs report should include a summary of the discussions about the pair's shared history, as well as any relevant observations about body language and the general interaction between donor and recipient.

Translators

77. Where 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. Form HTA IT (DC) should also be completed and accompany the referral letter (see Appendix D).

78. Any 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. 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.

Timing of referral and scheduling of surgery

79. Transplant teams should ensure they factor in sufficient time for both the IA assessment and HTA approval process to be completed, when scheduling provisional surgery dates. Relevant timescales are outlined in paragraphs 82–84.

The assessment process

Preparing for an IA assessment

80. To assess any potential living donor, a written referral, accompanied by copies of evidence of identity and relationship (where appropriate), is required from the clinician responsible for the donor. Information required in the referral letter is outlined in paragraphs 64–66.
81. If the necessary information is not included in the referral **or** evidence of relationship is unsatisfactory, the correct material should be obtained from the clinician responsible for the donor or the living donor coordinator, **before** the IA assessment takes place.

Timescales and accepting referrals

82. An appointment should be made to see the donor and recipient within a month of referral. In addition, if the use of an independent translator is required, they should be booked for the time of the assessment.
83. Before accepting a referral for a case, IAs should make sure that they will be able to:
 - undertake the assessment within one month of referral

- submit their report to the HTA within 10 working days of the assessment
 - be accessible in the five working days following the submission of their report, in case the HTA Transplant Approvals Team needs to contact them for further information or clarification
84. It is important that leave arrangements are taken into account when scheduling assessments, as delays may result in scheduled surgery not being able to proceed. If an IA considers they may not be able to undertake assessments or submit reports within the above timescales, or they are on leave in the five days following submission to the HTA, it may be advisable to ask the transplant team to find an alternative IA for that case.

Translators

85. Where a translator has been required in discussions between the transplant team and the donor and / or recipient, and will be needed for an IA interview, this should have been noted in the referral letter from the clinician.
86. Any 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. 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.
87. Any translator used during an IA interview should complete and sign form HTA IT (IA) (see appendix D). The translator's name and address will also need to be included in the IAs assessment report to the HTA (see paragraphs 77–78).

Cultural / ethnic factors

88. Where the IA is of a different cultural or ethnic background to the donor and / or recipient a health professional colleague of that cultural / ethnic background can be present at the interview to ensure these differences are considered. They should be independent of the donor and recipient.

Undertaking an IA assessment

Interviewing donors and recipients

89. The IAs responsibility is to interview the donor and recipient separately and together and to produce a report based on that interview. The exceptions to this are:
- If the potential recipient is a child. The donor should still be interviewed separately, but the child and the person with parental responsibility for the child can be seen together by the IA, even when the person with parental responsibility is also the potential donor.
 - In certain very rare circumstances it may be considered that an interview with a young child recipient is not necessary, either due to extreme logistical difficulties, or due to the very young age of the recipient (e.g. under two years old). However, in the majority of cases, the assessment should involve the recipient where possible.
 - The donation is a non-directed altruistic donation, where only the donor needs to be seen.
90. In cases where the recipient is an adult lacking capacity, the recipient should be seen separately from the donor where possible. The recipient can be accompanied by a carer to help them, and the IA, with the assessment.

Purpose and content of the IA assessment

91. The assessment should enable the IA to ascertain whether the following requirements have been met:
- A registered medical practitioner has explained to the donor the nature of the medical procedure in question, and the risks involved. (See appendix E for information on relevant morbidity and mortality risks).
 - The donor understands the nature of the medical procedure and the risks, as explained by the registered medical practitioner:
 - During an assessment, when ascertaining whether the donor understands the nature of the procedure and the risks

involved, IAs should ensure that the donor has fully understood the implications of these risks, as well as confirming that they are aware of relevant mortality and morbidity risks in statistical terms.

- Additionally, if IAs are made aware of any specific risks to a particular donor, they should ensure that the donor has properly considered these. A reference that the risks and implications have been discussed should be included within the IAs report to the HTA.
 - Any other wider implications for the donor and their dependent relatives have been discussed and understood (e.g. the risks to both donor and recipient and the effect upon leave arrangements from work and caring arrangements for the donor and their dependent relatives during the donor's convalescence period)
 - The donor has the capacity to consent, and has consented to the removal of the organ or part-organ in question
 - The donor's consent was obtained free from any duress or coercion or the offer of any other inducement
 - There is no evidence of an offer of reward (see paragraphs 55–59 for further information)
 - The donor understands that they are entitled to withdraw consent at any time and understands the consequences of withdrawal for the recipient
 - The donor-recipient relationship is as stated, where directed organ donation is involved. This will usually require appropriate supporting evidence, examples of which are given in paragraphs 67–76
 - There were no difficulties in communicating with the donor and / or recipient. If there were difficulties, details of how these were overcome will need to be noted within the IAs report. Guidance on translators can be found in paragraphs 77–78.
92. In cases of **paired / pooled donation** the following additional points should be explored:
- Ensure the donor and recipient are fully aware of the process involved, that they will not know the identity of the other pair before

donation and transplantation, and that they are aware of the wider implications; for example, if one kidney is not able to be removed or be transplanted. More information can be found in the NHSBT leaflet '*Paired living kidney donation*'.

- Explore whether the media have been or are likely to be involved in the process and the implications of this for the donor and recipient and their families. Further information and guidance on the media can be found at appendix G.

93. 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, i.e. that under no circumstances will either the recipient or the donor know of each other's identity before donation and transplantation, and that they may never know of each other's identity. More information can be found in the NHSBT leaflet '*Altruistic living kidney donation*'.
- Be satisfied that the donor has no evidence of current or past mental illness that affects their ability to donate altruistically with full, informed consent.
- Explore whether the media has been or is likely to be involved in the process and the implications of this for the donor and recipient.

After the IA assessment

Further information or clarification

94. Following an assessment, if an IA believes they need to see further documentary evidence of identity or relationship, or they have not yet had access to a non-directed altruistic donor's psychiatric report, then they should arrange to see this documentation **before** submitting their report to the HTA.

95. There is no requirement to write or file the report in the donor's case notes. The IA is not required to keep a copy of their own notes or the report, unless it is a requirement of his/her Trust / hospital, or they wish to for their own records. The IA will be able to search for an electronic copy of their submitted report via the online system.

96. If any concerns arise as a result of the IAs interviews with the donor and / or recipient, for example, about the donor's understanding of the risks of the procedure or whether they have consented under duress, the IA may wish to take further action before submitting their report to the HTA. For example, they may ask to see the donor and / or recipient again, or they may want to suggest other steps be taken, such as the donor's clinician explaining the risks of the procedure to them again.
97. If an IA is at all unsure about a case, they can contact the HTA Transplant Approvals Team for support, and to discuss what action may be appropriate. Again, this should be done **before** submitting the report to the HTA.

Timescales

98. Following an assessment, IAs must submit a report of their assessment to the HTA Transplant Approvals Team within 10 working days.
99. If for any reason (e.g. if an IA is waiting to see further documentary evidence to confirm a stated relationship), the report cannot be submitted within 10 working days, the IA should inform both the transplant team and the HTA Transplant Approvals Team.

Completing and submitting the assessment report

Accessing the report system

100. The HTA has created a secure online system, accessed via the HTA website, for the submission of IA reports. Each IA is given a username and password. The system allows IAs to write reports electronically and save them as many times as they wish before submitting it to the HTA www.hta.gov.uk
101. Separate guidance is available for IAs using the online submission system, which is available from the HTA website: <http://www.hta.gov.uk/donations/organdonations/independentassessors.cfm>.

Completing a report

102. The report is designed to ensure that IAs can confirm whether all the relevant requirements of the Act and Regulations have been met, and to provide supporting commentary and evidence using free text sections.

103. The report is split into seven main sections. These are:

Section A

Donor and recipient information, as well as details of the type and category of the transplant.

Within this section, IAs are required to provide details of the photographic and / or documentary evidence they have seen to confirm identities, and the relationship of donor to recipient / partner (except in cases of altruistic donation). Details of **all** documentation seen should be recorded within the report. In cases of genetically related directed donation, IAs should always note in the report if they have not been able to see copies of birth certificates, and explain what alternative evidence was provided.

Section B

Transplant unit and centre details, and names and contact details of the living donor coordinator(s) and clinician responsible for the donor.

Section C

Confirmation of whether the donor is a child under 18 or an adult without capacity. In Scotland, children and adults without capacity are not able to act as organ donors, but it should still be confirmed in such cases that this is not applicable within section C of the report.

Section D

Confirmation of whether there were any communication difficulties with the donor and / or recipient. In cases where there were difficulties (e.g. language), details should be provided of how these were overcome (e.g. use of translator). Where a translator was used, the name and address of the translator need to be provided.

Section E

Details of the registered medical practitioner who explained the nature of the procedure, the risks involved and the wider implications to the donor.

Within this section, IAs need to provide details of the donor's understanding and acceptance of the nature of the procedure, risks and any other wider implications (e.g. the effect upon dependent children or other relatives, leave arrangements for

work, provision made for any required support during recovery period).

Additional information is required in this section in cases of paired / pooled or non-directed altruistic donation.

For paired / pooled donation, IAs should give details of the pair's understanding of the process involved, the wider implications of the process (e.g. that the other pair could withdraw consent, or that one transplant may be successful while the other one may not) and that they will not know the identity of the other pair.

For non-directed altruistic donation a summary should be provided of discussions with the donor which enabled the IA to confirm that the donor understood the meaning of non-directed altruistic donation (i.e. that under no circumstances will either the recipient or donor know of each other's identity before donation and transplantation). IAs should also provide details of how they are satisfied that the donor does not have evidence of current or past mental illness that could affect their ability to give valid consent to altruistic donation.

It is not sufficient in this section for IAs to just state that donors understand the procedure, its risks and wider implications. An explanation of how the discussions satisfied them of this must also be provided.

Section F

Confirmation that, where applicable, the donor and recipient were seen separately and together, and that the donor understands that they are able to withdraw consent at any time up until the operation.

Within this section, IAs also need to provide details of the discussions they had in order to determine that there was no evidence of duress or coercion, or of an offer of reward, affecting the donor's decision to give consent.

It is not sufficient in this section for IAs to just state that there was no evidence of coercion or reward; an explanation of how the discussions satisfied them of this must also be provided.

Section G

Declaration by the IA confirming they have undertaken the assessment in accordance with the requirements of the Act and HTA guidelines. IAs are able to recommend that a donation should be approved, should not be approved or that further scrutiny should be undertaken by the HTA. IAs must also give a brief summary.

Submitting a report

104. Before submitting a completed report through the online submission system, IAs should double check the contact details included within the report to ensure they are correct. This is because email notifications of the submission of the report, and of the HTA's decision on the case, are automatically generated using the details provided within the report.
105. Once submitted, the IA will receive an email notification that the report has been received by the HTA.

Contingency report system

106. Should the online submission system be unavailable for any reason, the process for submitting reports is as follows:
- if the system cannot be accessed online, IAs should retry after a few hours and if still unavailable, again the following day
 - if the system still cannot be accessed, complete a contingency version of the report using the word template which can be downloaded from the HTA website:
http://www.hta.gov.uk/db/documents/2007-04-01_IA_contingency_report_form_updatedMK.doc

The report should then be submitted by email, post or fax:

- email your reports to transplants@hta.gov.uk with **IA form** in the subject line; or
- send a copy by fax to:
Attention: **Transplants**
Fax number: 020 7211 3430
Subject: Solid Organ Transplant

- or, send a hard copy to:
Transplants
Human Tissue Authority
15–17 Furnival Street
London EC4A 1AB

107. This information is also provided in the ‘Guidance for the online submission system’, which is available on the HTA website:
www.hta.gov.uk.

The HTA approval process

108. Following submission, an IA report will be reviewed by the HTA Transplant Approvals Team who will establish whether it is a case they can assess themselves or a case that requires approval by an HTA panel.

Clarification and further information

109. The Transplant Approvals Team will also review the report to ensure that all necessary information has been included and that there is sufficient information within the report for the HTA Transplant Approvals Team or panel to make a decision.

110. If further information or clarification is required, the HTA Transplant Approvals Team will contact the IA within two working days of submission of the report to request this information. The IA should seek to provide this information within three working days.

111. As outlined in paragraph 82–84, it is essential that IAs are accessible in the days following submission of a report in case further information is required.

112. Before accepting a referral for a case, IAs should make sure they will be accessible in the five working days following the submission of the report. If the HTA needs to contact an IA to obtain further information or clarification, any delay may affect the date of scheduled surgery.

113. Where a case is referred to an HTA panel, the panel may also request further documentation or information to assist their decision making. The HTA Transplant Approvals Team will act as the liaison between panels and IAs. This additional information may include:

- documentary and / or photographic evidence of a relationship
- form HTA IT(IA) when an independent translator has been used
- a copy of the original referral letter from the clinician responsible for the donor; or
- where appropriate, the psychiatrist's report

HTA turnaround times

114. A decision will be made on cases assessed by the HTA Transplant Approvals Team within five working days. This working day target begins when the Transplant Approvals Team have all the necessary information they need to make a decision, not from the day the IA submits the report.
115. Cases to be assessed by an HTA panel will be referred to the panel by the HTA Transplant Approvals Team within five working days, once all necessary information has been provided. Panels then have 10 working days in which to consider the case and make their decision.
116. It is important that both IAs and transplant teams bear these timescales in mind when scheduling referrals, assessments and provisional surgery dates.

Emergency out of office hours approvals

117. On the very rare occasion where there is a clinical reason for an immediate decision to be made outside office hours (for example, in cases of fulminant liver failure), NHSBT should be contacted on 0117 975 7575 in the first instance. The duty officer will then be able to provide details of the appropriate HTA personnel to assess the case.

Approval period

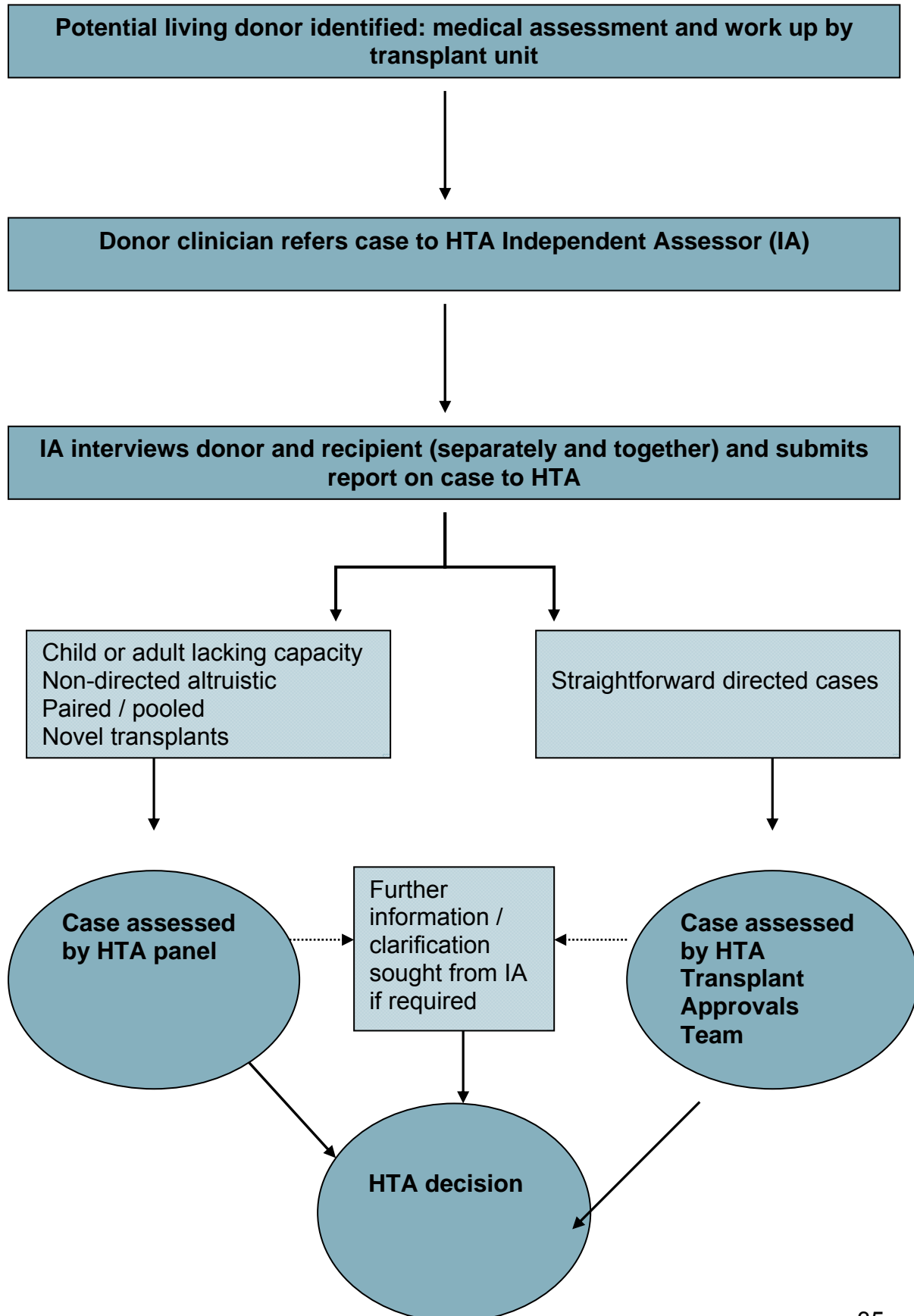
118. If HTA approval is given, the living donor transplant must go ahead within six months of the approval date. If the operation does not go ahead within six months, the donor and recipient will need to be seen again and an updated report from an IA will be required.
119. In exceptional cases, where a procedure has been scheduled just outside the six month deadline, the HTA may be able to extend the approval. The HTA Transplant Approvals team should be contacted as soon as possible in such cases, preferably before the expiry of the six

month deadline. Confirmation will be required that no significant changes have occurred since initial approval was given.

Review of HTA decisions

120. A donor or recipient, person acting on behalf of either, or the registered medical practitioner who caused the matter to be referred to the HTA, may ask for a review of any decision on a case made by the HTA. The process for doing this is laid out within the Regulations and requires a fresh decision to be made by the Authority.

Appendix A: Overview of Independent Assessment and HTA approval process



Appendix B: Scotland

- B1. The legal framework for living organ donation and transplantation is different in Scotland, and is set out in section 17 of the HT (Scotland) Act 2006. These provisions are supplemented by those in the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.
- B2. Under Scottish legislation, adults without capacity to make their own decisions and children (defined as persons who have not yet reached the age of 16) are only able to donate solid organs or part of an organ which has to be removed as part of a domino organ transplant operation. Unlike other forms of living organ donation, this form of donation is not regulated by the HTA.
- B3. Scottish law covering living organ donation by adults with capacity is broadly similar to that which applies in the rest of the UK, although in Scotland a person becomes an adult when they reach the age of 16.
- B4. Scottish Ministers have asked the HTA to regulate donation approvals on their behalf.

Appendix C: IA reaccreditation and performance assessment process

Timeframe for reaccreditation

- C1. Accreditation notices run concurrent with the financial year (i.e. 1 April – 31 March).
- C2. In **January** each year the HTA will conduct the official reaccreditation process, assessing all IAs' performance for the previous year (i.e. 1 January 2009 – 31 December 2009) against the agreed criteria.
- C3. IAs will then be notified of the outcome by **mid February**, and will need to successfully complete any refresher training required by the end of **March**.
- C4. Reaccreditation notices will be issued by **mid April** each year.

Criteria

- C5. The criteria that IAs will be marked against are contained in the table below. The criteria provide a robust and effective audit tool for assessing IA performance.

Quantitative assessment

- C6. A minimum number of assessments must be completed in order to ensure that IAs have had an opportunity to utilise their knowledge and skills in the preceding year, thus allowing them to remain well-versed on HTA reporting requirements.
- C7. IAs are required to have completed a minimum of **two** assessments within the year to meet the quantity criteria.
- C8. If an IA has been accredited during the accreditation year an allowance may be made in respect of the required number of reports to have been completed.

Performance assessment

- C9. Throughout the year, each case submitted to the HTA will be assessed against specified performance criteria. These criteria include assessment of both the accuracy and completeness of the IAs report and the conduct of the IA in dealing with the case.

C10. The **assessment criteria** are as follows:

- a. Were there any inaccuracies or omissions in the factual information provided in the report which required clarification?

If inaccurate or incomplete information has been provided, the HTA will be unable to make a decision until further information has been provided by the IA, thus creating more work for the HTA and the IA, and unduly delaying a decision on a case.

- b. Were there any free text sections within the report which provided insufficient explanation or detail and required further information being sought?

If sufficient information has not been provided, the HTA will be unable to make a decision until further information has been provided by the IA, thus creating more work for the HTA and the IA, and unduly delaying a decision on a case.

- c. Was there any unexplained or unnecessary delay in either submission of the report or responses to requests for clarification or further information?

IAs act as representatives of the HTA and are therefore expected to act in a professional manner. This includes completing assessments and reports in a timely manner and being contactable and approachable should clarification be required. Reports should be submitted within 10 working days of the IA interview. If the HTA requests further information or clarification, this should be provided by the IA within three working days.

The HTA realises that on occasions there may be circumstances where an IA cannot provide additional information requested within this timeframe; for example, if the information is not immediately available. Such circumstances will be taken into account when assessing this criterion.

Please note that should an IA be unable to undertake an assessment due to other work/time constraints, this will not reflect negatively on his / her performance

- d. Was the IA unwilling to provide clarification or further information?

IAs act as representatives of the HTA and are therefore expected to act in a professional manner. This includes being contactable and approachable should clarification be required, and not displaying an unreasonable attitude toward the HTA Transplants Approvals Team and / or approval process.

- e. Did the IA demonstrate a lack of understanding of the necessary process or requirements which created difficulties in the assessment of the case?

The role of the IA is to represent the HTA in an independent capacity in order to satisfy the requirements of the Act. In order to satisfactorily carry out this role it is important that the IA remains well versed in the requirements of the Act and Regulations, and the approvals process.

C11. In the case that none of the issues outlined within the assessment criteria arises, the case will be assessed as 'green'. If the answer to either (a) or (b) was yes and further information had to be sought, the case will be assessed as 'amber'. Please note that cases will be assessed as 'amber' where information is missing from a report and the HTA is unable to assess the report without further information from the IA; it does not refer to those times where the HTA may need to discuss a difficult or complex case in more detail with the IA.

C12. If the answer to any of (c), (d) or (e) was yes and there were difficulties in assessing the case, the case will be assessed as 'red'.

C13. If at any time during the year an IA achieves four consecutive cases assessed as 'amber' or two consecutive cases assessed as 'red', this will be escalated to the HTA's Transplantation Working Group (TWG) for decision on whether any action should be taken, such as writing to the IA about areas of performance that require improvement. We envisage such action would be taken very rarely.

C14. For **reaccreditation** purposes, in the case that:

- an IAs performance record has included two consecutive 'reds' or four consecutive 'ambers'; or
- an IAs overall performance record for the year demonstrates over 50% amber and / or red cases; the IA will be deemed not to havemet the necessary standard of performance and will be

escalated to TWG for decision on whether refresher training is required

C15. This approach ensures that reaccreditation works on an exceptions basis. Considering each case on an individual basis allows various factors to be taken into account, such as whether performance has improved following any action taken during the year following escalation to TWG, or whether there were particular difficulties in any case which resulted in an 'amber' or 'red' assessment.

Refresher training

C16. Where refresher training is required this will consist of completing specified sections of the e-learning package. Where it is identified that an IA has had the same performance issue(s) recur throughout the year, this will be highlighted in the letter informing them of the need to complete refresher training.

Appendix D: Forms and documentation

D1. Included in this appendix are the following form templates:

- **Form HTA RF (DC):** HTA Model Referral Form for Clinician to Independent Assessor for living donor transplantation
- **Form HTA IT (DC):** To be completed where the assistance of a translator has been required by the clinician responsible for the donor
- **Form HTA IT (IA):** To be completed where the assistance of a translator has been required by the Independent Assessor

Form HTA RF (DC)

(HTA Model referral form for clinician to Independent Assessor for living donor transplantation)

Dear..... [IA]

**Re: Name, DOB, reference number
Address (potential donor)**

**Name, DOB, reference number
Address (potential recipient)**

I would be grateful if you could provide an independent assessment for this donor-recipient pair whom I and my colleagues have counselled and assessed as a prospective kidney / liver / other (insert details) [*delete as appropriate*] donor, in accordance with the HTA codes of practice and 'Guidance for transplant teams and Independent Assessors'.

Salient information which you may require is given below.

Section 1: Family history and relevant social information (include place of birth, nationality, UK residential status any other relevant information)

Section 2: Donor information (include confirmation of medical and psychological suitability for surgery; confirmation that appropriate clinical investigations have been carried out with details of these; and explanation of procedure, choice of operation and kidney to be removed)

Section 3: Recipient information (include diagnosis, modality of treatment for organ failure and relevant health history)

Section 4: Evidence of relationship (please detail the evidence you have seen that confirms the relationship of the donor to the recipient. Be sure to enclose copies of this evidence)

Section 5: Requirements under HTA Guidance

Please note that if ‘no’ is answered in response to any of the statements below, further detail should be provided below.

Requirement	Confirmation
Comprehensive written and oral information provided to donor by registered medical practitioner	Y / N
Donor and recipient understand the relevant issues and there is evidence of informed consent	Y / N
Donor understands chances of success, potential complications / risks to recipient and any wider implications	Y / N
Donor understands effects of donation and convalescence period	Y / N
Donor has consented voluntarily (i.e. there is no evidence of coercion or duress affecting the donor’s decision to consent nor any evidence of financial reward)	Y / N
Donor understands they can withdraw consent and the implications for recipient	Y / N
Use of an independent translator required	Y / N

Section 6: Any other concerns to be raised

Section 7: Please list the names of the people involved in the counselling and preparation of the donor. Please include the name and qualification of the medical practitioner who explained the procedure and risks to donor; if a translator was required (and if so, please send form HTA IT (DC) with the referral); and email contact details for the clinician responsible for the donor and the living donor coordinator.

Based on the information provided above I am satisfied / not satisfied [*delete as appropriate*] that the donor is making an informed decision to donate.

Thank you for seeing this donor and recipient. Please do not hesitate to contact me if you require any further information or clarification regarding the information provided above.

Yours sincerely,

Form HTA IT (DC)

(To be completed where the assistance of a translator has been required by the clinician responsible for the donor)

Declaration by translator

My full name is.....

and my address is.....

.....

I declare that:

1. I(print full name)

am a translator of(specify language)

2. I was not known either to the

prospective donor
(print full name)

or the prospective recipient
(print full name)

before being asked to translate on this matter.

3. I have translated all the discussion about the options, risks and benefits of the procedures, undertaken by the clinician responsible for the donor

.....
(name of registered medical practitioner)

with the donor and I believe that *he / she understands the purpose and content of that discussion.

.....
Signature Date

*delete as appropriate

Form HTA IT (IA)

(To be completed where the assistance of a translator has been required by the Independent Assessor)

Declaration by translator

My full name is.....

and my address is.....

.....

I declare that:

1. I(print full name)

am a translator of(specify language)

2. I was not known either to the

prospective donor
(print full name)

or the prospective recipient
(print full name)

before being asked to translate on this matter.

3. I have translated the interview conducted by the independent assessor

.....
(name of Independent Assessor)

with the donor and recipient and I believe that they both understand the purpose and content of that interview.

.....
Signature Date

Appendix E: Morbidity and mortality risks of living organ donation

E1. In living kidney donation, the kidney can be removed by an open procedure, a hand-assisted laparoscopic procedure or a total laparoscopic procedure; and the donor should be aware of which procedure they are having and why. In living liver donation, a segment of the liver is removed. In living lung donation, a segment of lung is removed from two separate donors for each recipient.

E2. For living kidney donation, the risks are quantified in the British Transplantation Society / Renal Association guidelines (UK Guidelines for Living Donor Kidney Transplantation available at <http://www.bts.org.uk/transplantation/standards-and-guidelines>) and can be summarised as follows: the risk of peri-operative death is 1 in 3,000 and the risk of peri-operative major complications is 2-4%.

E3. For adult-to-adult living liver donation, the risks are quantified in the NICE Interventional Procedure Guidance document IPG194 Living-Donor Liver Transplantation reference. The risk of donor mortality is 1 in 200 and the risk of peri-operative major complications is 10 – 20%.

In adult-to-child living liver donation, the risks of donor mortality are between 1 in 500 and 1 in 1,000, and the risk of peri-operative major complications is 5 – 10%.

E4. For living lung donation the risks are quantified in the (NICE)'s National Institute for Clinical Excellence Interventional Procedure Guidance document IPG170, entitled 'Living donor lung transplantation for end-stage lung disease': http://www.nice.org.uk/page.aspx?o=ip_292. The international experience summarises the risks as follows: there have been no deaths reported in the world literature, although this reflects the relatively low number of procedures performed, and the risk of peri-operative major complications is up to 20%. However, in patients undergoing lobectomy of the lung for cancer, there is a recognised mortality rate of 2 - 4% (Guidelines on the Selection of Patients with Lung Cancer for Surgery-British Thoracic Society and Society of Cardiothoracic Surgeons of Great Britain and Ireland Working Party Thorax 2001: 56: 89 – 108).

Appendix F: Information about living donor transplant leaflets

The HTA leaflet 'Information about living-donor transplants' is available on the HTA website (www.hta.gov.uk) in the following languages:

English

Welsh

Urdu

Gujarati

Punjabi

Hindi

Bengali

Should you require copies of the leaflet in English to be sent to you, please contact the HTA Transplant Approvals Team on transplants@hta.gov.uk or 0207 211 3400.

Appendix G: Media policy

Introduction

The HTA is aware that there is often media interest in living donor transplantation and understands the benefit of this in raising public awareness of living donation.

The aim of this policy is to encourage media to cover the living donation process in a way that does not have a negative effect on the donation. It aims to ensure that:

- announcements by the HTA about altruistic, paired and pooled donations are not unduly influenced by the media or other parties
- any announcements are coordinated, and none of the parties involved are caught off-guard
- the interests of all parties involved in the donation processes are taken into account
- any issues about decision making are discussed

The Act requires the HTA to inform the public about activities within our remit and we often do proactive media work in the area of living donation. We will do our best to inform you of our actions in a timely way when they relate to transplants happening at your unit. Should you want to know more about our activities in this area you can get in touch with the HTA Communications Directorate (see section below).

We are aware that every transplant is different and that a situation may arise where it is not appropriate to follow these guidelines. If this happens we would encourage you to contact the HTA Communications Directorate as soon as possible to discuss how best to proceed.

Media announcements by HTA, hospitals or Trusts (in Scotland, Acute Operating Divisions)

If your unit is planning to make a media announcement, such as a press release about living donation, we ask that you inform the HTA before the media is contacted. Media announcements about a decision made by the HTA should be announced only by the HTA, and not any other party. NHSBT

has a role in promoting transplantation which differs from that of the HTA and we recommend they are also kept informed about media announcements.

Should your unit be involved in a type of living donor transplant that is a UK 'first', such as a pooled transplant that has not been performed before, we ask that you contact the HTA at the earliest opportunity. We also request that any announcement is coordinated with all parties concerned.

Media contact with transplant units, IAs or Trusts or hospitals

IAs and transplant teams may be contacted by media about living donor transplants. Where this interest focuses on the independent assessment process or the role of the HTA we ask that you make the following information available to the HTA Communications Directorate:

- the name of the journalist
- contact details (phone and email)
- the request
- what the issue is and their view on it
- the deadline
- the name and contact details for a representative of the Hospital Trust's communications department

In a Hospital Trust, it is likely to be their policy that media interest triggers contact with their Trust's communications team. Contact details for the HTA Communications Directorate should be provided to them. It may also be helpful if NHSBT media office is informed. Media can also be pointed to any information that is in the public domain, for example the living-donor transplant leaflet or the HTA website (www.hta.gov.uk), or the NHSBT website (www.uktransplant.org.uk).

Media contact with HTA or NHSBT about new forms of transplantation

It is possible that the media may approach you in relation to the new forms of transplantation, such as altruistic, paired or pooled donation. If you are approached please inform the HTA's Communications Directorate to ensure that media coverage does not have a negative effect on the donation process.

Specific issues relating to altruistic, paired or pooled donation

Media involvement could influence a donor's decision to proceed with a donation, particularly in relation to duress, coercion and reward. If the media have had any involvement in the process, you should always investigate this

during your interview with the donor and recipient. Other issues to be aware of before a paired and altruistic donation are as follows:

- no payment should be made to donors
- donors or pairs should remain anonymous until after the transplant

Should media want to report on a potential transplant before it has taken place, the following conditions should be adhered to:

- names of donors / recipients should be changed and it should be stated that they have been changed
- images of donors / recipients should be disguised; for example, silhouettes should be used, or photographs taken from the back
- the location of donors / recipients should not be too specific; for example, the region can be given but not the city or town they are from. For rarer transplants, such as altruistic donor transplants, even a region may reveal identity and this should be considered before proceeding with media
- locations of the transplant centres involved should not be made available to the donors or recipients
- the dates of the transplant and the centres involved should not be given in media coverage. Should a media release be issued with these details ahead of the transplant, the information should be under a strict embargo until the transplant has taken place

Following these steps should protect anonymity of all parties ahead of the transplant. A case in which donor and recipient anonymity was compromised prior to transplant has been brought to our attention. A couple from a paired transplant found out the identity of the other couple through media coverage. This led to anxiety for the couple involved as they were aware that this information may jeopardise the transplant proceeding. This situation could also lead to donors or recipients feeling pressured into continuing with the transplant.

Social networking sites, blogs and other types of new media are becoming increasingly common and the principles above should be applied. Potential donors and recipients should be discouraged from writing about their experiences online if they, or their locations, could be identified ahead of the transplant.

Documentaries about living donor transplantation

Documentary makers may be interested in following the process of a living donor transplant from start to finish, particularly new types of transplant such

as altruistic, paired or pooled. If this is the case you should consider the following:

- the HTA should be informed as soon as possible
- anonymity of the parties involved must be retained before of the transplant
- being involved with filming should not influence whether the donor / recipient goes ahead with the transplant. This can be explored during the IA process
- after the transplant goes ahead, the first contact with donors / recipients after the operation should be made by the transplant team rather than directly by the journalist. Donors / recipients should be given the option of whether they would like to continue with filming at this point
- donors / recipients should not feel pressured to take part, should know they can drop out of the filming process at any time, and should know they are not obliged to do follow-up media after the documentary is screened unless they want to
- although donors / recipients can pull out of the filming process at any time, they should be aware that once they have taken part in filming and signed a release form, this footage may be used even if they drop out of the process (unless agreed otherwise before filming takes place)
- donors / recipients should be aware that if they agree to take part they may discover the identity of the other parties involved subsequent to broadcast

Parties involved may also want to explore with the production company or television channel whether the documentary has already been commissioned and, if it has not, consider whether to invest their time in a project that may not go ahead. They may also want to explain the timescales involved in following a transplant, and that there are cases where, even when HTA approval has been given, the transplant does not go ahead.

What to do if something goes wrong with a living donor transplant

Living donation carries a risk of mortality, and major and minor complications. Should something go wrong with a transplant, this has the potential to adversely affect the living donor system. Therefore, we would suggest the following principles are adhered to:

- those involved in transplantation should work with their media offices and the HTA to develop lines-to-take for media should something go wrong

- all parties should be informed before you respond to the media and everyone should be kept informed of any developments
- should you refer to the role of the HTA in these circumstances, please use the wording in our key messages guide to describe our role. We would also ask that you send us the contact details of the journalist that you have spoken to. Our key messages guide can be found at: www.hta.gov.uk/publications/guidetoourkeymessages.cfm

Other issues

If there is any disagreement between parties about a decision by the HTA, it is important that a discussion takes place between the unit and the HTA before any media activity is undertaken. Communication between all parties on such occasions is key.

Key HTA messages

In general, the key HTA messages in relation to transplantation are:

- our regulation protects patients' interests and supports professionals
- informed consent, freely given, is the fundamental principle of the Human Tissue Act
- our living organ transplant approval scheme is successful and professionals, families and the public can have confidence in it
- the HTA's role is ensuring that the nature of the risk and the procedure is explained to, and understood by, the patient.

Contact details

The contact details for the HTA Communications Directorate are as follows:

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Appendix H: Confidentiality

- G1. The information provided in the IA reports is clearly of a sensitive and confidential nature.
- G2. The Data Protection Act aims to secure the right of individuals to privacy by protecting information that is held about them. Any public authority, which includes the HTA, that handles personal data, must comply with the data protection principles which control how such data is processed.
- G3. These principles state that data must be:
- 1) Fairly and lawfully processed
 - 2) Processed for limited purposes
 - 3) Adequate, relevant and not excessive
 - 4) Accurate
 - 5) Not kept for longer than is necessary
 - 6) Processed in line with your rights
 - 7) Secure
 - 8) Not transferred to countries without adequate protection.
- G4. IA reports contain information other than the personal information. In cases a person identified in the report requests information about themselves, the HTA could redact the information that did not apply and send them the data that applied only to them.
- G5. If a member of the public makes a request for information about another living individual, such as requesting details related to the donor and / or recipient in the IA report, this would be handled under the Freedom of Information (FOI) Act. Data protection considerations will still apply and the HTA will not have to provide the information if the disclosure would breach the data protection principles (as stated above). In the case of the IA report, data principles 2 and 7 would apply. To substantiate this, under section 41 of the FOI Act, there is an exemption relating to information provided in confidence. The HTA could therefore apply this exemption as well as quote data protection considerations, if there was a request from a member of the public for access to an IA report.