



Human Tissue Authority

The Quality and Safety of Organs Intended for Transplantation: a documentary framework

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The HTA's regulatory framework

1. The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501) (the Regulations) transpose into UK law the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Directive).
2. Commission Implementing Directive 2012/25/EU sets out rules for the transmission of information when organs are exchanged between Member States. These requirements have been transposed into UK law via the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (see paragraphs 92 to 108 of this document).
3. The Human Tissue Authority (HTA) is the Competent Authority for the implementation of the Directive across the United Kingdom.

Licensing under the Regulations

4. For the purposes of licensing by the HTA, there are two separate groups of activity detailed in the Regulations – procurement and transplantation. Each includes a number of individual activities, described as follows.
 - a. Procurement activities may include one or more of the following:
 - i. donor characterisation;
 - ii. organ characterisation;
 - iii. preservation of an organ;
 - iv. making arrangements to transport an organ; and
 - v. retrieval of an organ.
 - b. Transplantation activities may include one or more of the following:
 - i. organ characterisation;
 - ii. preservation of an organ;
 - iii. making arrangements to transport an organ; and
 - iv. implantation of an organ.

5. The applicant for a licence must state on the licence application form which activity or activities they wish to undertake. Multiple activities, both procurement and transplantation, can be carried out under a single licence.
6. Any person, that is an individual or corporate body, carrying out any of the above activities must apply for an HTA licence to authorise that activity prior to its commencement. From 27 August 2012, it is a criminal offence to conduct an activity without a licence. Once granted, any proposed variation to a licence (including adding licensable activities) may not be undertaken until an application has been made to, and granted by, the HTA.
7. Where this document refers to an HTA licence, this means a licence granted by the HTA under the Regulations. Where this document refers to HTA licences granted under different legislation, this will be specified. Guidance and information on the licensing process can be obtained on the [HTA's website](#).
8. The **HTA DIRECTS under Regulation 6** that the licence holder gives notice to the HTA of a named contact for each clinical area or speciality under the licence. Suitable contacts should be determined by each licence holder taking into account the governance and structure of their establishments. The licence holder should ensure that the HTA is informed of any changes to these contact details.
9. Licences granted under the Regulations apply to persons (corporate bodies or individual people), rather than premises. In practice, this means that the staff employed by licensed corporate bodies (such as trusts, or NHS Blood and Transplant) or licensed individuals can conduct a licensable activity in a range of locations that are authorised by their employer. For example: Specialist Nurses - Organ Donation (SNODs) are employed by NHS Blood and Transplant (NHSBT) and are authorised to carry out licensable activities through NHSBT's licence, regardless of the premises on which they carry out the licensed activities.
10. Licences granted by the HTA under the Regulations will be audited on a regular basis to ascertain compliance with the requirements of the Regulations, including statutory conditions and Directions given by the HTA. These audits may combine aspects of self-assessment and / or site visits.

The framework for the quality and safety of human organs intended for transplantation

11. This document is designed to support corporate bodies or individual people who are licensed, or intending to be licensed, under the Regulations. It forms part of the regulatory framework and specifies how the requirements for the quality and safety of

organs intended for transplantation shall be ensured to secure compliance with the Directive.

12. This framework document describes the requirements for licence holders including:
 - a. Statutory requirements as set out in the Regulations, including **statutory conditions** of the licence. These will be specified as such.
 - b. Directions issued by the HTA:
 - i. The HTA is required to issue Directions on a range of matters as specified in Schedule 2 of the Regulations. These Directions are issued under **Regulation 11** of the Regulations, and are specified as such; and
 - ii. The Regulations also allow the HTA to issue Directions as it considers necessary to ensure compliance with the Directive. These Directions are issued under **Regulation 6** of the Regulations, and are specified as such.
 - c. Guidance issued by the HTA under Regulation 12.

Directions under the Regulations and the Human Tissue Act 2004

13. Directions issued under the Regulations are part of the regulatory framework for ensuring the quality and safety of organs intended for transplantation. Directions relate to how operational activities must be carried out by persons working under the licence in order to maintain the quality and safety of organs.
14. Directions issued by the HTA are mandatory requirements for anyone holding a licence. Directions apply in England, Scotland, Wales and Northern Ireland under Regulation 2.
15. The HTA also has powers under regulation 6(2)(d) of the Regulations, which applies paragraphs 2(4)(c) to (f) and (5) of Schedule 3 of the HT Act to issue directions that deal with the following matters:
 - a. The type of information that relates to the carrying-on of the licensed activity, how this must be recorded, how long it must be kept, to whom it must be provided and how often.
 - b. The fee to be paid for the activity being licensed.

NHSBT assisted functions

16. In its role as the Competent Authority, the HTA has an agreement with NHSBT to assist it with the following functions (as permitted by regulation 21 of the Regulations):
 - a. Supervise the exchange of organs between the UK and other countries. The HTA will ensure that NHSBT meets the requirements laid down in the Directive, particularly in relation to the traceability of organs and the quality and safety requirements, and the Implementing Directive, which sets out provisions for the transfer of information when organs are exchanged
 - b. Keep records and make reports concerning procurement organisations and transplantation centres. This will require NHSBT to:
 - i. Keep the data needed to ensure traceability at all stages of the chain from donation to implantation or disposal;
 - ii. Keep a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted; and
 - iii. Publish an annual report on the activities of procurement organisations and transplantation centres.
 - c. Keep a register of living donors for the purposes of endeavouring to ensure the follow-up of living donors.
 - d. Manage a reporting system for serious adverse events and serious adverse reactions (SAEARs). This will require NHSBT to:
 - i. Manage a system to report, investigate, register and transmit information about SAEARs associated with organ donation and transplantation; and
 - ii. Notify the HTA of any SAEAR associated with organ donation and transplantation, the steps being taken to manage the SAEAR and confirmation that all actions associated with the SAEAR have been concluded.

Donor consent

Legal requirements for consent and authorisation

17. Obtaining or verifying the consent or authorisation requirements for organ donation for transplantation must be carried out in accordance with the relevant legislation:

In England and Northern Ireland:

- a) Deceased organ donation: The removal, storage and use of organs and tissue for transplantation is governed by the Human Tissue Act 2004, this includes Vascularised Composite Allografts. Before organs and tissue can be removed, stored or used for transplantation, appropriate consent must be obtained. Appropriate consent is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative or the consent of a person in a 'qualifying relationship' with them immediately before they died. For further advice on the regulation of deceased donation please refer to the [HTA Codes of Practice](#) and associated guidance.
- b) Living organ donation: The law requires that appropriate consent is in place in order to remove, store and use organs and tissue from living donors for transplantation. Once this consent has been obtained it remains an offence under the Human Tissue Act to remove an organ from a living person for the purpose of transplantation unless the HTA gives permission. For further advice on the regulation of living organ donation and the relevant requirements please refer to the [HTA Codes of Practice](#) and associated guidance.

OR

In Wales:

- a) Deceased organ donation: A system of deemed consent for organ donation after death is operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This means that when there is no record of a person's decision on organ donation, their consent to organ donation will be deemed to have been given, unless a person with a close relationship provides evidence that the person would not have wanted to be an organ donor. The HTA has published a [Code of Practice](#) on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent system.
- b) Living organ donation: The Human Transplantation (Wales) Act 2013 relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA's regulation of living organ donation. For information on the

regulation of living organ donation in Wales please refer to the [HTA Codes of Practice](#) and associated guidance.

OR

In Scotland:

- a) Deceased organ donation: Deceased donation is governed by the Human Tissue (Scotland) Act 2006. Before organs and tissue can be removed, stored or used for transplantation, authorisation must be obtained.
 - b) Living organ donation: Living donation is governed by the Human Tissue (Scotland) Act 2006. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland. However, the HTA assesses applications for living organ donations on behalf of Scottish Ministers who delegated this responsibility to the HTA. For more information, please refer to the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (Scottish Statutory Instrument (SSI) 2006/390).
18. It is a **statutory condition** of a licence for retrieval of an organ, that procurement is carried out only after all of the requirements relating to consent and authorisation have been met.
 19. Further advice and guidance can be found in the HTA's Codes of Practice available on the [HTA website](#).

Statutory requirements, directions and guidance for licence holders

The role of the licence holder

20. It is a **statutory requirement** (Regulation 10) that the licence holder secures compliance with:
 - a. conditions of the licence; and
 - b. HTA directions imposed on the licence.
21. It is a **statutory condition** of all licences that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent, suitably qualified or trained, and provided with the training necessary to perform their tasks. The HTA considers 'directly involved' to include any healthcare personnel whose duties directly affect the quality and safety of an organ, and would not include, for example, hospital cleaning staff.
22. It is a **statutory condition** of all licences that medical activities are performed under the advice and guidance of a registered medical practitioner, and that there are

operating procedures in place demonstrating how this requirement is complied with (National operating procedure NOP005: Activities to be performed under the advice and guidance of a registered medical practitioner in deceased and living donation is available at <http://www.odt.nhs.uk/>). **The HTA DIRECTS under Regulation 11** that such medical activities include:

- a. review and interpretation of donor and organ characterisation information and data;
- b. inspection and assessment of the organ at the time of retrieval;
- c. surgical retrieval of an organ;
- d. flushing an organ with preservation solution;
- e. packing the organ for transport, either on a machine or in a box; and
- f. surgical implantation of an organ.

National operating procedures

23. The Regulations provide that a number of operating procedures must be put in place by licence holders under Schedule 1 as statutory conditions of any licence. NHSBT has developed a suite of national operating procedures available at <http://www.odt.nhs.uk/>.
24. The national operating procedures are deemed sufficient to meet the requirements of the Regulations. Establishments may choose to adopt the national operating procedure where available, adapt it for local use or implement their own procedures to meet the requirements. Where a national operating procedure is available, this will be highlighted in the text of this document. Whether adopting and adapting the national operating procedures or implementing a bespoke set of procedures, it is the establishment's responsibility to ensure that the documents remain valid and are updated to reflect any changes in local or national procedures. Additionally, establishments should ensure that any updates made to the national procedures by NHSBT are reviewed and incorporated into the establishment's own procedures as appropriate.
25. National operating procedures have been developed which cover the following areas:
 - a. Management of a serious adverse event or reaction;
 - b. Reporting serious adverse events and reactions and the management measures taken;
 - c. Ensuring the data required to ensure traceability of organs is kept for 30 years from the date of retrieval;

- d. Storing information on organ and donor characterisation for a period specified by the HTA;
 - e. Activities which must be performed under the advice and guidance of a registered medical practitioner;
 - f. The management of procurement material and equipment;
 - g. Verification of consent (or authorisation in Scotland) requirements prior to retrieval;
 - h. Transfer of information on donor and organ characterisation;
 - i. Verification of donor identity and the collection of donor and organ characterisation prior to implantation;
 - j. Ensuring the integrity of the organ during transport and a suitable transport time;
 - k. Labelling of shipping containers; and
 - l. Ensuring that organs transported are accompanied by a report on the organ and donor characterisation.
26. **The HTA DIRECTS under Regulation 6** that these operating procedures must be adopted, with local amendments as appropriate, or alternative procedures developed which meet the regulatory requirements.

Donor and organ characterisation

27. Donor and organ characterisation must be undertaken under the authority of an HTA licence.
28. Donor and organ characterisation refers to the collection of relevant information on the characteristics of the donor or organ, needed to evaluate the donor or organ's suitability for donation or transplantation in order to undertake a proper risk assessment and minimize the risks for the recipient and optimise organ allocation. It does not include the clinical decision making on whether to proceed to transplant.
29. Although testing facilities themselves are not required to be licensed, establishments undertaking donor and organ characterisation must ensure that laboratories used for testing meet the requirements set out in paragraph 37- 43.
30. It is a **statutory condition** of a licence for donor characterisation or organ characterisation that where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other appropriate persons of a

deceased donor and has explained to such persons the importance of swift transmission of that information.

31. It is a **statutory condition** of a licence for donor characterisation or organ characterisation, that donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive (that is included as Part A of the appendix to this documentary framework) (see paragraphs 32 and 79 below).
32. Part A of the Annex to the Directive sets out the mandatory requirements for organ and donor characterisation. These are the minimum mandatory requirements for every procurement organisation and transplant centre. As these are minimum requirements, they may be exceeded in practice by licensed establishments where their own practice requires the collection of data in addition to that specified in Part A.
33. It is a **statutory condition** of a licence for donor or organ characterisation that donors and organs are characterised before implantation by the collection of the information specified in Part B of the Annex to the Directive, where this is considered appropriate by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner.
34. Part B is currently a non-mandatory, complementary data set of information for the characterisation of organs and donors to be collected in addition to the minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case. At any time Part B is amended, the HTA will send out a notification.
35. It should be noted that, if, according to a risk-benefit analysis in a particular case, including life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for implantation even where not all of the minimum data specified in Part A of Appendix A are available. This is a **statutory condition** of a licence for implantation (see paragraph 79). **The HTA DIRECTS under Regulation 6** that the decision relating to this risk-benefit analysis should be clearly documented, e.g. in the patient notes.
36. It is a **statutory condition** of a licence to keep information on donor and organ characterisation for a period specified by HTA in directions, and to have in place operating procedures demonstrating how this requirement is met (NOP001 Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation is available). **The HTA DIRECTS under Regulation 11** that the information, including any risk-benefit analyses, must be kept for 30 years after donation.

Testing

37. **The HTA DIRECTS under Regulation 11** that the tests required for donor and organ characterisation are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment. The HTA considers that laboratories which hold current Clinical Pathology Accreditation (CPA) or who have been accredited by the United Kingdom Accreditation Service (UKAS) to the internationally recognised standard ISO 15189:2012 will meet this requirement.
38. Laboratory accreditation status can be checked by visiting:
<http://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/>
39. **The HTA DIRECTS under Regulation 11** that for deceased donation, where an individual working under a licence is responsible for ordering the tests for the purpose of carrying out donor or organ characterisation, they should endeavour to use only laboratories accredited by CPA or UKAS.
40. In endeavouring to only use laboratories which hold CPA or UKAS accreditation, the HTA would expect licence holders to establish the accreditation status of laboratories that are frequently used for donor or organ characterisation, and to review and update this information on a regular basis.
41. Licence holders should not use a laboratory with an unknown or unaccredited status unless justified on the basis of risk to the quality and safety of the organ or to the recipient. This should be documented for reference in event of a serious adverse event or serious adverse reaction.
42. **The HTA DIRECTS under Regulation 11** that for living donation, only CPA or UKAS accredited laboratories should be used, unless by doing so there is a risk to the donor or recipient which would outweigh the risk of using a non-accredited laboratory or one with an unknown status, e.g. due to time constraints in an emergency liver donation.
43. **The HTA DIRECTS under Regulation 11** that licence holders put in place procedures to ensure that information on organ and donor characterisation reaches the person who will be implanting an organ in a recipient within a time period that would not compromise the quality and safety of the organ (NOP001 Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation is available).

Retrieval of organs for implantation

44. Retrieval of organs for implantation must take place under the authority of an HTA licence.
45. It is a **statutory condition** of a licence for retrieval of an organ, that the procurement is only carried out after all of the requirements relating to consent (and authorisation in Scotland) have been met.
46. It is a **statutory condition** of the licence for a procurement activity, including retrieval of an organ, that procurement material and equipment which could affect the quality and safety of an organ are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices, and that operating procedures are in place demonstrating how this requirement is complied with (NOP004 Management of procurement material and equipment in deceased and living donation and transplantation is available).
47. **The HTA DIRECTS under Regulation 11** that material and equipment used in organ retrieval must, at a minimum:
 - a. meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended), where these apply; and
 - b. be subject to a validated cleaning and sterilisation procedure for removal of infectious agents when reusable instruments are used.

Living donors

48. It is a **statutory condition** of a licence for the procurement activity of retrieval of an organ, that endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.
49. The HTA considers that reasonable endeavours would include providing information to living donors and referral centres on how to identify and report any event or serious adverse reaction that may result from the donation. Donors should be encouraged to discuss this information with their families and GPs, where appropriate. This is particularly relevant for donors from overseas who travel to the UK to donate.
50. Transplant centres should explain to donors the importance of informing the centre of any change in contact details.

51. Following British Transplantation Society (BTS) guidelines, life-long follow up on an annual basis is recommended after living donation. This can be offered locally or at the transplant centre according to the wishes of the donor.
52. All usual forms of contact with the donor must have been attempted in the form of phone calls and letters. If such attempts at contact fail, a recorded letter should be sent to the last known address of the donor. Where these attempts to contact living donors have been made without success, the HTA would consider that reasonable endeavours had been made.

Requirements for organs and tissues used for purposes other than implantation

53. For reasons described below, additional tissues and cells may be removed at the same time as the retrieval of organs for implantation. Consideration must be given to ensuring that any tissues and cells removed from an organ donor are dealt with appropriately, depending on the circumstances.
54. *Tissues and cells to directly support organ transplantation* e.g. accessory vessels. These are essential to re-establishing functionality in the recipient and therefore retrieval of those tissues and cells is covered by the same licence as retrieval of organs for implantation.
 - a. Storage of those tissues and cells for use in the organ recipient to support organ transplantation does not require an HTA storage licence. Licence holders should consider as guidance provided in the Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment, which sets out storage requirements for tissues and cells.
 - b. Storage of those tissues and cells for less than 48 hours does not require an HTA licence. However, should those tissues and cells be stored for more than 48 hours for use in a patient other than the primary recipient, they must be stored under a storage licence issued under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (SI 2007 No. 1523).
 - c. If at any point those tissues and cells are to be used for a purpose other than to support a specific donation they will fall into the regulatory framework relevant to that use. A list of scheduled purposes under the Human Tissue Act can be found [here](#). More information on activities that require a licence under the HT Act can be found [here](#).
 - d. Persons seeking to use tissues and cells in a manner other than to support the original organ recipient should assure themselves that the relevant licence(s) and consent or authorisation are in place, prior to commencing the alternative use.

55. *Tissues and cells for transplantation from a donor of both tissues and organs* e.g. heart valves procured for transplant from a deceased kidney donor. These tissues and cells are not organs, as defined in the Directive, and therefore do not come within this regulatory framework for the quality and safety of human organs intended for transplantation. Tissues and cells for transplantation must be procured under a procurement licence in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (SI 2007 No. 1523) or under a Third Party Agreement with an HTA licensed tissue establishment.
56. *Tissues and cells or organs removed for use for a scheduled purpose, such as research, under the Human Tissue Act 2004* e.g. removal of a kidney for use in a research project. The Human Tissue Act 2004 applies to England, Wales and Northern Ireland.
- a. These tissues and cells do not fall into the regulatory framework for organs and, if from the deceased, must be removed under a licence issued under the Human Tissue Act. (Note: Human Tissue Act licences are premises specific).
 - b. The Human Tissue Act sets out a number of scheduled (specified) purposes for which tissue can be stored. Relevant material, that is material, other than gametes or embryos, which consists of or includes human cells, being stored for use for a scheduled purpose must be stored on HTA-licensed premises (subject to any applicable licensing exemptions). Further guidance can be found in the HTA's code of practice for research.
57. *Tissues and cells or organs removed for use in research, education and training or audit under the Human Tissue (Scotland) Act* e.g. removal of a kidney for use in a research project in Scotland.
- a. The Human Tissue (Scotland) Act 2006 defines specific activities for which human tissue from deceased donors can be stored and used. A licence is not required for these activities in Scotland; however, authorisation must be in place for these activities to be lawful.
 - b. Removal requires appropriate authorisation to be in place and must be carried out by an authorised person in accordance with the Human Tissue (Scotland) Act 2006.

Organ preservation

58. Preservation of an organ must be undertaken under the authority of an HTA licence.

59. It is a **statutory condition** of the licence for a procurement activity, including preservation of an organ, that material and equipment which could affect the quality and safety of an organ are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices, and that operating procedures are in place demonstrating how this requirement is complied with (NOP004 Management of procurement material and equipment in deceased and living donation and transplantation is available).
60. **The HTA DIRECTS under Regulation 11** that material and equipment used in organ preservation must, at a minimum:
- a. meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended), where these apply; and
 - b. be subject to a validated cleaning and sterilisation procedure for removal of infectious agents when reusable instruments are used.
61. **The HTA DIRECTS under Regulation 11** that records of perfusion fluid coming into contact with organs must be made and retained as part of the organ traceability requirements. The manufacturer and batch number should be recorded on the appropriate HTA A and B forms (please see paragraph 91), which will be updated for this purpose. The HTA further DIRECTS under Regulation 11 that these forms must be returned to NHSBT within 7 days, who will keep the data for the required 30 years.
62. Licence holders should make themselves aware of the traceability requirements in paragraphs 86 - 91 in this document.

Making arrangements for the transportation of organs

63. Making arrangements for the transportation of organs for transplantation must be carried out under the authority of an HTA licence.
64. It is a **statutory condition** of the licence for making arrangements to transport an organ, that the integrity of the organ is ensured during transport and that the transport time is suitable to ensure the quality and safety of the organ.
65. It is a **statutory condition** of a licence for making arrangements to transport an organ, that there is an operating procedure in place to demonstrate how the requirement in paragraph 64 is complied with (NOP003 Packaging, labelling and transport of organs in deceased and living donation and transplantation is available).
66. A suitable transport time should be determined by the relevant dispatching and receiving licence holders, taking into account:

- a. organ type;
 - b. total ischaemic time relevant to the organ;
 - c. any current published guidance on recommended maximum transport times; and
 - d. any other relevant factors known to the licence holder.
67. Licence holders must ensure that the traceability requirements outlined in paragraph 89 relating to records of transportation are complied with.
68. **The HTA DIRECTS under Regulation 6** that the organ shipping container must be suitable for the transport of the specified organ, taking into account the required method of transport, and the conditions required to protect the safety and quality of the organ. Packaging must minimise the risk of contamination and must be able to preserve the organs at the specified temperature range for the identified maximum transit time. The packaging must also protect those handling or transporting the organs from potential biohazards.
69. It is a **statutory condition** of the licence for making arrangements to transport an organ (except where transportation is carried out in the same establishment) that the shipping container used for transporting organs must be labelled with the following information:
- a. Identification of the licence holder who retrieved the organ, and the place where the retrieval took place, including an address and telephone number for that place;
 - b. Identification of the establishment where the organ will be implanted in a recipient, including its address and telephone number;
 - c. A statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked 'HANDLE WITH CARE'; and
 - d. Recommended transport conditions, including instructions on keeping the container at an appropriate temperature and position.
70. **The HTA DIRECTS under Regulation 6** that for deceased donation, the shipping container must also be labelled with the telephone number of NHSBT Duty Office.
71. **The HTA DIRECTS under Regulation 6** that some information required on the shipping container referred in paragraph 69 above may be contained in a secure labelling area in cases of confidential or sensitive information if necessary.

72. It is a **statutory condition** of a licence for making arrangements to transport an organ that the organs transported are accompanied by a report on the organ and donor characterisation.
73. **The HTA DIRECTS under Regulation 6**, that this report may be provided electronically to the transplant surgeons where possible in order to maintain donor confidentiality.
74. It is a **statutory condition** of the licence for a procurement activity or for a transplantation activity of making arrangements to transport an organ that operating procedures are in place demonstrating how licence holders comply with paragraphs 69 and 72 (NOP003 Packaging, labelling and transport of organs in deceased and living donation and transplantation is available).
75. **The HTA DIRECTS under Regulation 6** that licence holders must ensure that any person or organisation transporting organs on their behalf is meeting the requirements of paragraphs 64 - 69 (including labelling) and 0 - 120 (serious adverse events and serious adverse reactions (SAEARs)). Such assurance may be given through contractual arrangements between the licence holder and the transport organisation setting out the required standards to be met during the transportation of organs.

Implantation

76. Implantation must be carried out under the authority of an HTA licence.
77. It is a **statutory condition** of a licence for implantation that, subject to paragraph 79 below, the following are verified before proceeding to implant an organ into a recipient:
- a. identification of the donor;
 - b. the collection of information specified in annex A and where appropriate, annex B of the Directive described in paragraphs 31 and 33 above; and
 - c. compliance with the statutory conditions of the licences required by paragraphs 64 - 75 above about the preservation and transportation of shipped organs.
78. It is a **statutory condition** of the licence for implantation that the licence holder has in place operating procedures to demonstrate how the requirements of a and b are complied with (NOP002 Verification of donor identity, consent/authorisation and organ and donor characterisation in deceased and living donation and transplantation is available).
79. It is a **statutory condition** of the licence for the transplantation activity of implantation, where any of the information described in Part A is not available, to conduct a risk-benefit analysis to determine whether the expected benefits for the recipient of the

organ outweigh the risks posed by the lack of any information. **The HTA DIRECTS under Regulation 6** that the decision relating to this risk-benefit analysis should be clearly documented, e.g. in the patient notes.

80. Licence holders should make themselves aware of the traceability requirements in paragraphs 86 - 91 in this document.

Disposal

81. Disposal is not a licensable activity. However, the requirements for traceability and Serious Adverse Events and Serious Adverse Reactions (SAEARs) outlined in this document must be observed. The following guidance may be of use to establishments. Where an organ is to be destroyed, this should be in accordance with the establishment's own policy for the sensitive disposal of organs.
82. Disposal options for an organ which cannot be used for implantation include, but are not limited to:
- a. with appropriate consent, use of the organ for a scheduled purpose under the HT Act (e.g. research, public display, training and education);
 - b. with appropriate authorisation, use of the organ for research, education and training, or audit under the HT (Scotland) Act;
 - c. re-implantation into the living donor;
 - d. return to the donor's family, and
 - e. destruction of the organ e.g. by incineration/cremation/burial.
83. Should a nominated recipient deteriorate and be unable to accept the organ, and consent for donation to another recipient has been given, implantation of the organ into another person (including re-implantation into the living donor) is not considered to be disposal. The requirements of paragraphs 58 - 80 must be followed for the preservation, transportation and implantation of that organ.
84. Where an organ is to be stored for use for a scheduled purpose (other than transplantation) under the HT Act, this must be done with appropriate consent and stored under an HT Act licence or applicable licensing exemption.
85. Where an organ is to be disposed of, establishments should keep records in order that they may report data as required by paragraph 86. Licence holders should note that NHSBT currently requires data on disposal, that is the final placement of an organ where it is not used for transplantation, to be collected and submitted to the UK Transplant Registry within 21 days of disposal to ensure full traceability is maintained.

Traceability

86. It is a **statutory condition** of a licence for a procurement or transplantation activity that the data required to ensure the traceability of organs is kept for 30 years after donation, and that there is an operating procedure in place to demonstrate how this requirement is complied with (a national operating procedure will be available).
87. **The HTA DIRECTS under Regulation 11** that licence holders must implement an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
88. All establishments are reminded of their obligations under the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260), and the Human Tissue (Scotland) Act (Maintenance of Records and Supply of Information Regarding the removal and use of body parts) Regulations 2006, to supply information to NHSBT regarding the removal and receipt of transplantable material. Such information is provided by means of the current HTA A and B forms, which can be obtained from NHSBT.
89. **The HTA DIRECTS under Regulation 11** that the data to ensure traceability is recorded using the appropriate HTA A and B forms. The HTA further DIRECTS under Regulation 11 that these forms must be returned to NHSBT within 7 days, who will keep the data for the required 30 years.
90. **The HTA DIRECTS under Regulation 11** that licence holders must ensure that a record (date and time) of the transportation of organs arriving and/or leaving the establishment is kept as part of the traceability information, including the consignment record documentation if available. This is required to be kept for 30 years after donation.
91. **The HTA DIRECTS under Regulation 11** that records of perfusion fluid coming into contact with organs must be made and retained as part of the organ traceability requirements. The manufacturer and batch number should be recorded on the appropriate HTA A and B forms, which will be updated for this purpose. The HTA further DIRECTS under Regulation 11 that these forms must be returned to NHSBT within 7 days, who will keep the data for the required 30 years.

Exchange of organs between EU Member States

92. Exchange of organs between different countries is one way of increasing the number of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplantation. Advances in organ preservation and transport techniques can only serve to increase the number of organ exchanges

which take place. Available organs should be able to cross borders without unnecessary problems and delays.

93. Commission Implementing Directive 2012/25/EU sets out rules for the transmission of information when organs are exchanged between Member States. The requirements have been transposed into UK law via the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014, and cover the transmission of information:
- a. on donor and organ characterisation
 - b. for the traceability of organs
 - c. for the reporting of serious adverse events and reactions.
94. NHSBT will act as the lead organisation for the UK involved in transmitting information for the exchange of organs. However, there may be times when transplant centres are also involved in transmitting information. Where any organisation sends or receives information for the exchange of organs they must do so in accordance with the following HTA Directions.
95. **The HTA DIRECTS** that information transmitted for the exchange of organs must comply with the following procedural rules. The information must:
- a. be transmitted in writing, either electronically or by fax;
 - b. be written in a language mutually understood by the sender and the addressee or, if not possible, in a mutually agreed language, or if that is also not possible, in English;
 - c. be transmitted without undue delay;
 - d. be recorded and made available upon request;
 - e. indicate the date and time of the transmission;
 - f. include the contact details of the person or department to be contacted for further information regarding the transmission;
 - g. contain the following reminder: 'Contains personal data. To be protected against unauthorised disclosure or access'.
96. **The HTA DIRECTS** that, in urgent cases, information can be exchanged verbally, in particular for exchanges relating to donor and organ characterisation, and serious adverse events and reactions. These verbal contacts must be followed by a transmission in writing in accordance with the directions set out in this section.

97. **The HTA DIRECTS** that any establishment receiving information relating to the exchange of organs confirms receipt of that information to the sender, and such receipt should be transmitted in accordance with the general requirements set out in paragraph 95 above.

Information on donor and organ characterisation – deceased donation

98. Information to characterise the donor and the organ will normally be collected by the SN-OD in deceased donation, although in some cases the retrieving medical team may provide additional donor and organ characterisation information. Where organs are envisaged for exchange between member states, **the HTA DIRECTS** that the information collected to characterise the donor and the organ (as specified in paragraphs 31 – 34 and the Appendix to this documentary framework) is provided to NHSBT who will be responsible for transmitting the information to the appropriate body in the destination Member State prior to exchange of the organ.
99. Where some of the information required by paragraph 98 is not available at the time of the initial transmission and becomes available later, in order to allow due time for medical decisions, **the HTA DIRECTS** that this can either be:
- a. transmitted to the NHSBT duty office who will transmit the information to the destination Member State, or
 - b. transmitted directly by the SN-OD or retrieval team in the UK to the receiving transplant centre.
100. **The HTA DIRECTS** that, where additional donor or organ characterisation information is transmitted directly by the SN-OD or retrieval team to the receiving transplant centre as in paragraph 99b above, a copy of this information is retained locally by the SN-OD or recorded on the organ specific form.

Information on donor and organ characterisation – living donation

101. In the UK, organs from living donors are rarely exchanged with other European countries; however, this may become more routine in the future.
102. For directed living donations the donor and organ characterisation information will normally be collected by the living donor co-ordinator in conjunction with the transplant medical team, and be held within the donating and/or recipient centres. In cases where the organ will be sent to, or received from, another Member State **the HTA DIRECTS** that this information can be exchanged directly between the donating and recipient hospitals.

103. In cases where the organ will be sent to, or received from, another Member State as part of an organ sharing scheme (i.e. non-directed altruistic donation, paired/pooled donation or altruistic donor chain), **the HTA DIRECTS** that the donor and organ characterisation information required for registration is transmitted to NHSBT Information Services at the time of donor registration. NHSBT will be responsible for transmitting the information to the appropriate body in the destination Member State. Subsequent to matching, **the HTA DIRECTS** that the donor or recipient hospitals will exchange information to inform the preparation and scheduling of the donation and implantation surgery.
104. Establishments should continue to transmit donor and organ characterisation information to NHSBT by way of the HTA A and B forms following the donation and transplant.

Information to ensure the traceability of organs

105. NHSBT will be responsible for ensuring that the information required to ensure traceability of organs from donor to recipient is transmitted to the appropriate Member State.
106. Establishments have an obligation under the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 (S.I. 2006/1260), and the Human Tissue (Scotland) Act (Maintenance of Records and Supply of Information Regarding the removal and use of body parts) Regulations 2006, to supply information to NHSBT regarding the removal and receipt of transplantable material. Such information is provided by way of the current HTA A and B forms.

Reporting of serious adverse events and reactions

107. Establishments should refer to paragraphs 111 – 120 of this documentary framework regarding the reporting of serious adverse events and reactions to NHSBT (acting on behalf of the HTA). These requirements also apply where there is a serious adverse event or reaction that is suspected to relate to an organ received from or sent to another Member State.
108. NHSBT will be responsible for sending and receiving information to / from other member states regarding serious adverse events and reactions when organs are exchanged, and for transmitting any such information to transplant centres if required.

Exchange of organs with non-EU countries

109. Where an organ is sent to, or received from, a country which is not in the European Union, **the HTA DIRECTS** that licence holders must ensure that the traceability requirements outlined in paragraphs 86 – 91 of this document are complied with. Any identification system must ensure that organs can be traced from the donor to the recipient.
110. **The HTA DIRECTS** that any organs sent to, or received from, a country which is not in the European Union meet the quality and safety standards that are equivalent to those required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 and this framework document.

Serious adverse events and serious adverse reactions (SAEARs)

111. More detailed guidance on SAEARs can be found [here](#).
112. It is a **statutory condition** of a licence for a procurement or a transplantation activity:
- a. To have in place operating procedures for the management of a serious adverse event or a serious adverse reaction.
 - b. To rapidly report to NHSBT (acting on behalf of the HTA):
 - i. Relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation, which may be connected to those activities;
 - ii. The management measures taken with regard to such a serious adverse event or reaction.
113. **The HTA DIRECTS under Regulation 6** that serious adverse events occurring at the transplant centre that may influence the quality and safety of organs should also be rapidly reported to NHSBT (acting on behalf of the HTA).
114. The above procedures must ensure that:
- a. Staff responsibilities for the management of SAEs and SARs are clearly defined;

- b. Immediate actions can be taken to ensure damage limitation, including:
 - i. effective use of traceability information to ensure all organs, tissues and cells related to a particular donor or donation can be identified and recalled if necessary;
 - ii. having in place systems and procedures for communication with other establishments affected or implicated in the SAE/SAR, such as other licence holders and third parties.
115. It is a **statutory condition** of the licence for the procurement activity of retrieval of an organ that licence holders must have suitable arrangements in place to make endeavours to follow-up living donors:
- a. for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation;
 - b. to identify, report to NHSBT (acting on behalf of the HTA), and manage any event or reaction referred to in sub-paragraph a above.
116. **The HTA DIRECTS under Regulation 11** that the time period for notifying serious adverse events and reactions (i.e. the initial report) to NHSBT must be within 24 hours of the discovery of the SAE or SAR by the licence holder. In cases where an urgent notification and recall is required the establishment must telephone the Organ Donation and Transplant (ODT) duty office (01179 757575) immediately upon discovery of the SAE or SAR. Urgent notification would include cases where there are potential implications for other recipients.
117. **The HTA DIRECTS under Regulation 6** that third parties, such as those undertaking testing for donor characterisation or those undertaking transportation, must be instructed to report to the licence holder within 24 hours of their discovery of SAEs or SARs.
118. **The HTA DIRECTS under Regulation 6** that a follow-up report to NHSBT must normally be provided within 90 days. This report should include the results of any investigation and the corrective and preventative actions taken or planned to prevent recurrence.
119. Following notification of any SAE or SAR, the HTA may organise an audit of the licence holder or other establishment and may require the licence holder to carry out such control measures as are deemed appropriate.
120. **The HTA DIRECTS under Regulation 6** that all records associated with the SAE or SAR must be retained for 30 years after donation.

Termination of activities

121. **The HTA DIRECTS under Regulation 6** that the Licence Holder must notify the HTA as soon as possible in the event of termination of any licensable activities. Licence holders will be asked to complete a revocation form and submit this to the HTA one month prior to planned termination of activities.

Approved

Glossary

Authorisation, in respect of a donor in Scotland, means: where the donor is an adult with capacity to give authorisation, Part 1 of the Human Tissue (Scotland) Act 2006; or the authorisation or lack of unwillingness of the donor referred to in, the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (SI 2006/390).

Consent in respect of a donor in England or Northern Ireland, means appropriate consent in the Human Tissue Act 2004.

Consent in respect of a donor in Wales, means either deemed consent or express consent in the Human Transplantation (Wales) Act.

Deemed consent in respect of a donor in Wales under the Human Transplantation (Wales) Act, means that when there is no record of a person's decision on organ donation, their consent to organ donation will be deemed to have been given, unless a person with a close relationship provides evidence that the person would not have wanted to be an organ donor.

Directive means Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

Disposal means the final placement of an organ where it is not used for transplantation.

Donor means a person who donates one or several organs, whether donation occurs during lifetime or after death.

Donor selection means a process by which consent or authorisation is obtained or verified, and a potential donor is identified.

Donation means donating organs for the purposes of transplantation.

Donor characterisation means the collection of relevant information on the characteristics of the donor needed to evaluate the donor's suitability for donation, in order to undertake a proper risk assessment and to minimise the risks for the recipient, and optimise organ allocation.

Express consent in respect of a donor in Wales under the Human Transplantation (Wales) Act, means:

- the decision of a person when alive to either consent or not to consent to certain transplantation activities; or
- the decision of appointed representative/s on behalf of that person; or
- the decision of someone with parental responsibility (when the person is a child); or
- the decision of someone in a qualifying relationship with that person.

Implantation is considered by the HTA to mean the activity of transferring an organ into a recipient.

Implementing Directive means Commission Implementing Directive 2012/25/EU on information procedures for the exchange, between Member States, of human organs intended for transplantation.

Licence holder means a person who holds a licence under Schedule 1 of the Regulations.

Licensed activity in relation to a licence, means an activity which the licence authorises under Schedule 1 of the Regulations. Such an activity will either be a procurement activity or a transplantation activity.

NHSBT means NHS Blood and Transplant.

Organ means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

Organ characterisation means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability for transplantation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation.

ODR means the NHS organ donor register.

Operating procedures means written instructions describing the steps in a specific process, including the material and methods to be used and the expected end outcome.

Person means an individual or corporate body.

Procurement means a process by which a donated organ becomes available for transplantation.

Procurement activity means any of the following licensable activities, undertaken for the purposes of procurement:

- a) donor characterisation;
- b) organ characterisation;
- c) preservation of an organ;

- d) making arrangements to transport an organ; or
- e) retrieval of an organ.

Preservation means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation.

Recipient means a person who receives a transplant of an organ.

Registered medical practitioner means a medical practitioner who is registered and with a licence to practice by the General Medical Council.

Regulation 6 means regulation 6 of the [Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(SI 2012 No. 1501\)](#), authorising the HTA to give directions to a licence holder to ensure compliance with the Directive.

Regulation 11 means regulation 11 of the [Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(SI 2012 No. 1501\)](#), authorising the HTA to give directions to a licence holder as prescribed in Schedule 2 of the Regulations.

Retrieval is considered by the HTA to mean the activity of removing an organ from a donor.

Schedule 2 means Schedule 2 of the [Quality and Safety of Organs Intended for Transplantation Regulations 2012 \(SI 2012 No. 1501\)](#), requiring the HTA to give specific directions to ensure consistent compliance with the licensing conditions prescribed in Schedule 1 of those Regulations.

Serious adverse event means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which result in, or prolongs, hospitalisation or morbidity.

Serious adverse reaction means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Tests means laboratory-based tests for the purposes of determining donor and organ suitability for transplantation, including microbiological and virology screening, human leukocyte antigen (HLA) typing and cross-matching, and ABO blood grouping.

Traceability means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to:

- a) identify the donor and the licence holder who retrieved the organ from the donor;
- b) identify the licence holder who implanted the organ into the recipient;
- c) identify the recipient at the premises that the organ is implanted into the recipient;
and
- d) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.

Transplantation means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.

Transplantation activity means any of the following licensable activities, undertaken for the purposes of transplantation:

- a) organ characterisation;
- b) preservation of an organ;
- c) making arrangements to transport an organ; or
- d) implantation of an organ.

UK Transplant Registry means the register of organ donation and transplantation activities as held by NHSBT.

Appendix A: Organ and donor characterisation

Part A and part B below are reproduced directly from the Directive

Part A - Minimum data set

Information for the characterisation of organs and donors, which has to be collected for each donation in accordance with the section on organ and donor characterisation.

- a) The establishment where the procurement takes place and other general data
- b) Type of donor
- c) Blood group
- d) Gender
- e) Cause of death
- f) Date of death
- g) Date of birth or estimated age
- h) Weight
- i) Height
- j) Past or present history of IV drug abuse
- k) Past or present history of malignant neoplasia
- l) Present history of other transmissible disease
- m) HIV; HCV; HBV tests
- n) Basic information to evaluate the function of the donated organ.

Part B - Complementary data set

Information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

General data

Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

Donor medical history

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.