

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

**Published: April 2021**



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

---

## Contents

The HTA’s regulatory framework.....	4
Licensing under the Regulations .....	4
The framework for the quality and safety of organs intended for transplantation .....	6
Directions under the Regulations and the Human Tissue Act 2004 (HT Act).....	6
NHSBT assisted functions .....	7
Donor Consent.....	8
Legal requirements for consent and authorisation .....	8
Statutory requirements, directions and guidance for licence holders .....	10
The role of the licence holder.....	10
National operating procedures .....	11
Donor and organ characterisation .....	13
Testing .....	14
Retrieval of organs for implantation.....	16
Living donors.....	16
Requirements for organs and tissues used for purposes other than implantation.	17
Organ preservation .....	19
Making arrangements for the transportation of organs .....	19
Implantation .....	21
Disposal .....	23
Traceability.....	24
Exchange of organs with other countries .....	25
Information on donor and organ characterisation – deceased donation .....	26
Information on donor and organ characterisation – living donation.....	26
Information to ensure the traceability of organs .....	27
Reporting of serious adverse events and reactions (SAEARs).....	27
Exchange of organs with a third country .....	27
SAEARs.....	28
Termination of activities.....	30
Glossary .....	31
Annex A: Organ and donor characterisation .....	35
Minimum data set.....	35

Annex B - Complementary data set..... 36

## The HTA's regulatory framework

1. The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501), as amended, (the Regulations) set the standards for the quality and safety of organs intended for transplantation.

## Licensing under the Regulations

2. For the purposes of licensing by the HTA, there are two separate groups of activity detailed in the Regulations – procurement and transplantation. Each includes several 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.
3. The applicant for a licence must state which activity or activities they wish to undertake. Multiple activities, both procurement and transplantation, can be carried out under a single licence.
4. Any person, whether an individual or corporate body, carrying out any of the above activities must apply for an HTA licence to authorise that activity starting. It is a criminal offence to conduct an activity without a licence. Once granted, any proposed variation to a licence (including adding licensable activities) can only be undertaken once an application has been granted by the HTA.
5. 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 is specified. Guidance and information on the licensing process is on the [HTA's website](#).

6. The **HTA DIRECTS under Regulation 6** that the licence holder gives notice to the HTA of a named contact for each clinical area or specialty 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 on [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk).
7. 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 NHS Trusts, Health Boards 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.
8. 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 organs intended for transplantation

9. 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 of the Regulations can be met.
10. 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 are 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 to ensure the quality and safety of organs intended for transplantation. 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 (HT Act)

11. 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.
12. 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.
13. 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**

14. As permitted by regulation 21 of the Regulations, an agreement is in place through which NHSBT assists the HTA with the following functions:
- a) Supervise the exchange of organs between the UK and other countries. The HTA will ensure that NHSBT meets the requirements as set out in both sets of Regulations.
  - b) Keep records and make reports concerning procurement organisations and transplantation centres. This requires 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).
    - i. This requires NHSBT to:  
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

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

#### *In England:*

- a) Deceased organ donation: In May 2020, a system of deemed consent for organ and tissue donation after death became operational, as a result of the implementation of the Organ Donation (Deemed Consent) Act 2019. This means that when there is no record of a person's decision on organ and tissue donation, their consent can be deemed to have been given, unless evidence is provided that the person would not have wanted to be a donor. Deemed consent does not apply to those people that fall into an excepted group. For further advice, please see [Part two of Code of Practice E](#).
- 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 HT Act to remove an organ from a living person for the purpose of transplantation unless the HTA gives permission. For further advice, please see [Part one of Code of Practice F](#).

#### *In Wales:*

- a) Deceased organ donation: A system of deemed consent for organ and tissue 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 and tissue donation, their consent can be deemed to have been given, unless evidence is provided that the person would not have wanted to be an organ donor. Deemed consent does not apply to those people that fall into an excepted group. For further advice, please see the [Code of Practice on the Human Transplantation \(Wales\) Act 2013](#).
- 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 further advice, please see [Part one of Code of Practice F](#).



***In Scotland:***

- a) Deceased organ donation: In March 2021, a system of deemed authorisation for organ and tissue donation after death became operational, as a result of the implementation of the [Human Tissue \(Authorisation\) \(Scotland\) Act 2019](#). This means that when there is no record of a person's decision on organ and tissue donation, their authorisation can be deemed to have been given, unless evidence is provided that the person would not have wanted to be a donor. Deemed authorisation does not apply to those people that fall into an excepted group. For further advice, please see the [Organ Donation Scotland](#) website.
- 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 further advice please see the [HTA guidance for transplant teams, Independent Assessors and Accredited Assessors in Scotland](#).

***In Northern Ireland:***

- a) Deceased organ donation: The removal, storage and use of organs and tissue for transplantation is governed by the HT Act. 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, please see [Part two of Code of Practice F](#).
  - 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 HT Act to remove an organ from a living person for the purpose of transplantation unless the HTA gives permission. For further advice, please see [Part one of Code of Practice F](#).
16. 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.
17. Further advice and guidance can be found in the [Codes of Practice](#).

## Statutory requirements, directions and guidance for licence holders

### The role of the licence holder

18. 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.
19. 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.
20. 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 ([NOP005](#) Activities to be performed under the advice and guidance of a registered medical practitioner in deceased and living donation). **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

21. 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.
22. NHSBT has developed a [suite of national operating procedures](#) (NOPs). The NOPs are sufficient to meet the requirements of the Regulations once they have been adapted to reflect the establishment's local procedures. Whether adopting and adapting the NOPs or implementing a bespoke set of procedures, it is the establishment's responsibility to ensure that the documents remain valid and 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.
23. 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.

24. **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

25. Donor and organ characterisation must be undertaken under the authority of an HTA licence.
26. Donor and organ characterisation refers to the collection of relevant information on the characteristics of the donor or organ. This information is required to evaluate the donor or organ's suitability for donation or transplantation in order to undertake a proper risk assessment. This process minimises the risks for the recipient and optimises organ allocation. Data generated during any mechanical perfusion of organs used to determine the suitability of the organ is included within the definition of organ characterisation data. Data relating to mechanical perfusion must be kept, along with other donor and organ characterisation data, by the establishment for 30 years (see paragraph 34). It does not include the clinical decision making on whether to proceed to transplant.
27. 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 paragraphs 35 - 42.
28. Where a donor is deceased, it is a **statutory condition** of a licence for donor characterisation or organ characterisation to be collected. This must be by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner. They must endeavour to obtain information from the relatives, or other appropriate persons of the deceased donor. The importance of swift transmission of that information must be explained to those individuals.
29. 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 Annex A of this documentary framework (see paragraphs 30 and 78).
30. [Annex A](#) 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 [Annex A](#).
31. 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 Annex B, where it is considered appropriate by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner.

32. Annex B is a non-mandatory, complementary data set of information for the characterisation of organs and donors. This can be collected in addition to the minimum data specified in Annex A, based on the decision of the medical team and taking into account the availability of such information and the particular circumstances of the case. If Annex B is amended, the HTA will send out a notification.
33. 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 Annex A are available. This is a **statutory condition** of a licence for implantation (see paragraph 78). **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.
34. It is a **statutory condition** of a licence to keep information on donor and organ characterisation for a period specified by the 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). Establishments should also consider wider organisational policies and procedures when assuring themselves that systems are in place to keep donor and organ characterisation information for the required period, e.g. patient records retention policies. **The HTA DIRECTS under Regulation 11** that the information, including any risk-benefit analyses, must be kept for 30 years after donation.

## Testing

35. **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 that have been accredited by the United Kingdom Accreditation Service (UKAS) to the internationally recognised standard ISO 15189:2012 will meet this requirement.
36. Laboratory accreditation status can be checked against [the UKAS Directory of Accredited Organisations](#).
37. **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 UKAS.

38. In endeavouring to use laboratories that hold 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.
39. 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.
40. Establishments should consider relevant professional guidance regarding testing of living and deceased donors prior to organ retrieval, for example guidance published by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). Microbiological test results for a living donor should be available from a blood sample that has been taken up to 30 days prior to organ donation. More information is available on [SaBTO's Guidance on safety of organs for transplantation](#).
41. **The HTA DIRECTS under Regulation 11** that for living donation, only 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.
42. **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 into 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).

## Retrieval of organs for implantation

43. Retrieval of organs for implantation must take place under the authority of an HTA licence.
44. It is a **statutory condition** of a licence for retrieval of an organ that procurement is only carried out after all of the requirements relating to consent (authorisation in Scotland) have been met.
45. 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 international and national legislation and standards and guidelines on the sterilisation of medical devices. Operating procedures should be in place demonstrating how this requirement is complied with ([NOP004](#) Management of procurement material and equipment in deceased and living donation and transplantation).
46. Establishments should also consider wider organisational policies and procedures when assuring themselves that procurement material and equipment are suitable. For example, policies on purchase of medical devices and procedures to ensure materials used in procurement, such as perfusion fluids, are stored in suitable, monitored environments.
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) (UK MDR 2002), 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. Establishments are advised to include a reminder about reporting Serious Adverse Events and Reactions to the living donor's medical practitioner in the discharge letter. This is so that if the donor presented with any medical conditions which may have an impact for the organ recipient, the establishment can be contacted immediately so that the recipient can be followed up as necessary.

50. Transplant centres should explain to donors the importance of informing the centre of any change in contact details, or any medical conditions which may have an impact for the organ recipient.
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 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 (for example, the Regulations referred to above at point (b)). Please see the [list of scheduled purposes](#) under the HT Act.

More information on activities that require a licence under the HT Act is [available on our website](#).

- 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, and therefore do not fall within this regulatory framework for the quality and safety of 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 HT Act e.g. removal of a kidney for use in a research project. The HT Act 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 HT Act (Note: HT Act licences are premises specific).
  - b) The HT 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 is in the HTA's Code of Practice for Research.
57. Tissues and cells or organs removed for use in research, education, training, audit or quality assurance purposes under the Human Tissue (Scotland) Act 2006 (as amended by the Human Tissue (Authorisation) (Scotland) Act 2019) e.g. removal of a kidney for use in a research project in Scotland.
- a) The Human Tissue (Scotland) Act 2006, as amended, lists specific activities for which human tissue from deceased donors can be removed 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, as amended.

### **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 international and national legislation and standards and guidelines on the sterilisation of medical devices. Operating procedures should be in place demonstrating how this requirement is complied with ([NOP004](#) Management of procurement material and equipment in deceased and living donation and transplantation).
- 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) (UK MDR 2002), 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 (see paragraph 92). 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. Establishments should also assure themselves that perfusion fluids are stored in monitored environments that meet the manufacturer's recommended storage conditions.
- 63. Licence holders should make themselves aware of the traceability requirements in paragraphs 88 - 94 in this document.

### **Making arrangements for the transportation of organs**

- 64. Making arrangements for the transportation of organs for transplantation must be carried out under the authority of an HTA licence.

65. 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.
66. 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 is complied with ([NOP003](#) Packaging, labelling and transport of organs in deceased and living donation and transplantation).
67. 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.
68. Licence holders must ensure that the traceability requirements outlined in paragraph 93 relating to records of transportation are complied with.
69. **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.
70. 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.
71. **The HTA DIRECTS under Regulation 6** that for deceased donation, the shipping container must also be labelled with the telephone number of NHSBT Hub Operations.
72. **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.
73. 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.
74. **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.
75. 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).
76. **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 - 68 (including labelling) and 111 - 112 and 115 -124 (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

77. Implantation must be carried out under the authority of an HTA licence.
78. It is a **statutory condition** of a licence for implantation that 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 described in paragraphs 29 – 31 above; and

- c) compliance with the statutory conditions of the licences required by paragraphs 64 - 76 about the preservation and transportation of shipped organs.
79. 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 78 (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).
80. Establishments are also advised to record when the information required in paragraph 78 has been reviewed and by whom.
81. It is a **statutory condition** of the licence for the transplantation activity of implantation, where any of the information described in Annex 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.
82. Licence holders should make themselves aware of the traceability requirements in paragraphs 88 - 94 in this document.

## Disposal

83. Disposal is not a licensable activity. However, the requirements for traceability and SAEARs outlined in this document must be observed. Where an organ is to be disposed of, this should be in accordance with the establishment's own policy for the sensitive disposal of organs.
84. 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.
85. 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 above must be followed for the preservation, transportation and implantation of that organ.
86. 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.
87. Where an organ is to be disposed of, establishments should keep records to ensure they may report data as required by paragraph 84. Licence holders should note that NHSBT currently requires data on disposal to be collected and submitted to the UK Transplant Registry within 21 days of disposal to ensure full traceability is maintained.

## Traceability

88. 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.
89. Establishments should also consider wider organisational policies and procedures when assuring themselves that systems are in place to keep traceability information for the required period, e.g. patient records retention policies.
90. **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.
91. Establishments should be familiar with obligations under the HT Act (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.
92. **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.
93. **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.
94. **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. 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 with other countries

95. Exchange of organs between different countries is one way of increasing the number of organs available. Advances in organ preservation and transport techniques can only serve to increase the number of organ exchanges that take place. Organs should be able to cross borders without unnecessary problems and delays.
96. Exchange of organs between GB, NI and third countries should ensure that the below quality and safety standards are followed.
97. The Regulations cover the transmission of information:
  - a) on donor and organ characterisation;
  - b) for the traceability of organs; and
  - c) for the reporting of serious adverse events and reactions.
98. NHSBT is the 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.
99. **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 accesses.'
100. **The HTA DIRECTS under Regulation 6** 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.

101. **The HTA DIRECTS under Regulation 6** 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 above.

#### **Information on donor and organ characterisation – deceased donation**

102. 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 countries, **the HTA DIRECTS under Regulation 6** that the information collected to characterise the donor and the organ (as specified in paragraphs 30 - 33) is provided to NHSBT who will be responsible for transmitting the information to the appropriate body in the destination country prior to exchange of the organ.
103. 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 under Regulation 6** that this can either be:
- a) transmitted to the NHSBT Hub Operations who will transmit the information to the destination country, or
  - b) transmitted directly by the SN-OD or retrieval team in the UK to the receiving transplant centre.
104. **The HTA DIRECTS under Regulation 6** 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**

105. In the UK, organs from living donors are rarely exchanged with other countries; however, this may become routine in the future.
106. For directed living donations, the donor and organ characterisation information will normally be collected by the living donor coordinator 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 country **the HTA DIRECTS under Regulation 6** that this information can be exchanged directly between the donating and recipient hospitals.

107. In cases where the organ will be sent to, or received from, another country as part of an organ sharing scheme (i.e. non-directed altruistic donation, paired/pooled donation or altruistic donor chain), **the HTA DIRECTS under Regulation 6** 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 country. Subsequent to matching, **the HTA DIRECTS under Regulation 6** that the donor or recipient hospitals will exchange information to inform the preparation and scheduling of the donation and implantation surgery.
108. Establishments should continue to transmit donor and organ characterisation information to NHSBT using the HTA A and B forms following the donation and transplant.

### **Information to ensure the traceability of organs**

109. NHSBT will be responsible for ensuring that the information required to ensure traceability of organs from donor to recipient is transmitted to the appropriate country.
110. Establishments have an obligation under the HT Act (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. This information is provided using the HTA A and B forms.

### **Reporting of serious adverse events and reactions (SAEARs)**

111. Establishments should refer to paragraphs 115 - 124 regarding the reporting of SAEARs to NHSBT (acting on behalf of the HTA). These requirements also apply where there is a SAEAR that is suspected to relate to an organ received from, or sent to, another country.
112. NHSBT will be responsible for sending and receiving information to / from other countries regarding SAEARs when organs are exchanged, and for transmitting any such information to transplant centres if required.

### **Exchange of organs with a third country**

113. Where an organ is sent to, or received from, a third country, **the HTA DIRECTS under Regulation 11** that licence holders must ensure that the traceability requirements outlined in paragraphs 88 – 94 of this document are complied with. Any identification system must ensure that organs can be traced from the donor to the

recipient.

114. **The HTA DIRECTS under Regulation 11** that any organs sent to, or received from, a third country meet the quality and safety standards that are equivalent to those required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 as amended, and this framework document.

### **SAEARs**

115. More detailed guidance on SAEARs can be found [on our website](#).
116. 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.
117. **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).
118. 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.

119. 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.
120. **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 NHSBT Hub Operations (0117 9757580) immediately upon discovery of the SAE or SAR. Urgent notification would include cases where there are potential implications for other recipients.
121. **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.
122. **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.
123. 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.
124. **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**

125. **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.

## Glossary

**Authorisation** in respect of a donor in Scotland, authorisation has the same meaning as consent.

**Consent** in respect of a donor in Northern Ireland, means appropriate consent under the Human Tissue Act.

**Consent** in respect of a donor in Wales or England, means either deemed consent or expressed consent under the Human Transplantation (Wales) Act 2013 or the Organ Donation (Deemed Consent) Act 2019 respectively.

**Deemed consent** in respect of a donor in England or Wales, means that when there is no record of a person's decision on organ and tissue donation after death, their consent can be deemed to have been given, unless evidence is provided that the person would not have wanted to be a donor.

**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.

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

**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.



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

**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.

## **Annex A: Organ and donor characterisation**

### **Minimum data set**

Information for the characterisation of organs and donors, which must be collected for each donation.

- 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.

## **Annex B - Complementary data set**

Information for the characterisation of organs and donors to be collected in addition to minimum data specified in Annex A, based on the decision of the medical team. This should take into account the availability of the 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