Code of practice 8
Import and export of human bodies, body parts and tissue
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Introduction

The legislation and the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) covers England, Wales and Northern Ireland with the exception of the provisions relating to the use of DNA, which also apply to Scotland. The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006.
2. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) implement the European Union Tissue and Cells Directives (EUTCD). The HTA is the Competent Authority in the UK under the Q&S Regulations, which cover the whole of the UK, including Scotland.

3. The HTA is also the Competent Authority in the UK for the implementation of the European Union Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Directive). The requirements of the Directive are transposed into UK law via the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q & S Organs Regulations).

4. The HTA’s remit in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 (Ref: NHS HDL (2006) 46) and the relevant codes of practice. Relevant guidance from Wales and Northern Ireland is referenced throughout the codes.

5. On 1 December 2015 an opt-out system for organ donation after death will become operational in Wales, the legislation on this is the Human Transplantation (Wales) Act 2013. The HTA has drafted a Code of Practice to provide advice and guidance on the Human Transplantation (Wales) Act. At the time of drafting this Code of Practice, the Code of Practice on the opt-out system in Wales had not yet gained Parliamentary or Welsh Assembly approval, however a copy of the draft document is available on the HTA website.

6. The Code of Practice on the Human Transplantation (Wales) Act 2013 should not be relied on until the law becomes operational on 1 December 2015. Up until that time the HTA’s Code of Practice 2 is the relevant document.

About the codes of practice

7. The codes of practice give practical guidance to professionals carrying out activities which lie within the HTA’s remit. They may also be of interest to members of the public. These editions of the codes have been revised to reflect our experience of regulation and to update references to guidance from other organisations.

8. These Codes of Practice give guidance to those carrying out activities which lie within the HTA’s remit under the Human Tissue Act 2004 and lay down the standards expected. Failure to follow the guidance is not in itself an offence under the HT Act. Nevertheless, failure to observe the principles set out in the Code may influence licensing decisions made by the HTA.

10. There are specific requirements relating to the import and export of tissues and cells covered by the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These are not included in this Code as they are outlined in the HTA’s Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

Scope of the code

11. The remit of the HTA within the HT Act provides the statutory basis for the HTA to prepare a Code on “the import or export, of –

   1. the body of a deceased person, or
   2. relevant material which has come from a human body,” for use for a Scheduled Purpose.

12. The import and export of relevant material is not a licensable activity under the HT Act. However, the storage of the material once it is imported may be licensable if this is for a Scheduled Purpose.

13. This Code indicates appropriate practice for licensed establishments (see Part 1). In addition, it sets out good practice for individuals and establishments not undertaking licensable activities under the HT Act (see Part 2) but nonetheless involved in the import and export of human bodies, body parts and tissue used for other purposes. The Code also covers existing standards which individuals and organisations involved in the practice of import and export may already be following.

14. As the Code is designed for different groups of users to consult, parts of its guidance are repeated, as users may in practice only refer only to the section(s) which apply to their own particular circumstances.

15. This Code applies to the import and export of human bodies, body parts and tissue, including:

   1. human bodies or body parts removed after death and
   2. tissue removed at biopsy and during surgery.

16. From the deceased, this includes material that is fresh, frozen, plastinated, dried, embalmed or preserved in some way. From living people, this includes tissue for research (including paraffin blocks and slides).
17. The geographical scope of “import” and “export” according to the HT Act is as follows:

1. “import” means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;
2. “export” means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

18. There are a number of exceptions to the application of this Code. The Code does not apply to whole bodies or parts of bodies that:

1. fall outside the HT Act e.g. gametes and embryos created outside the human body, and material that does not contain cells;
2. come under the jurisdiction of the Coroner England, Wales and Northern Ireland, or the Procurator Fiscal in Scotland;
3. are being brought into, or removed from, England, Wales and Northern Ireland for lawful disposal here or abroad;
4. are historical human remains, or human remains incorporated into artefacts, which are more than 100 years old, and imported by museums;
5. are from the living and only intended for diagnostic use.

19. Where a death occurs outside Northern Ireland and the body is brought back to the province, the coroner has jurisdiction to hold an inquest if the body may be said to have been ‘found’ in his district. With respect to cremation of a body in Scotland, if the death occurred in England and Wales, the application to cremate is deemed to be made in accordance with the equivalent Regulations applicable in England and Wales and the Scottish Executive has no involvement. However, where the deceased died in any place ‘furth of Scotland and outwith the UK’,

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1 There is at present no restriction on bringing bodies or human remains into the UK. However, disposal of such remains by cremation will usually require authorisation by the coroner in whose district the remains are (in England, Wales and Northern Ireland) and it is advisable that the coroner’s office is contacted if cremation is being considered to determine whether such authorisation is necessary. It is very unlikely that a doctor based in the UK would be in a position to complete the necessary cremation documentation, as required by law, if the individual died outside the UK. Moreover, if the presence of such a body, or sufficient parts of a body, is reported to a coroner in England and Wales, and the death is one which would have required an inquest if the death had occurred here, the coroner is required to hold an inquest, notwithstanding that the death occurred abroad. Sections 1(1) and 1(2) of the Coroners and Justice Act 2009, which does not apply in Northern Ireland, confirm that if the cause of death has been given and it is a natural cause, the coroner does not have to conduct an investigation into that person’s death. However, if the cause of death is unknown, or the cause of death is violent or unnatural, the coroner will conduct an investigation into the person’s death and, if required, will request a post mortem examination. If the post mortem reveals that the deceased died of natural causes, and the coroner thinks it is not necessary to continue the investigation into the death, the coroner must discontinue the investigation as outlined in section 4(1) of the Coroners and Justice Act 2009. This does not apply if the coroner has reason to suspect that the deceased died a violent or unnatural death, in which case the coroner must hold an inquest into the death, as confirmed in section 6 of the Coroners and Justice Act 2009.
authority to cremate must be given by Scottish ministers in accordance with the Cremation Scotland Regulations 1935. No body may be removed out of England and Wales without the prior authorisation of the coroner (or of the Procurator Fiscal in Scotland). Whether such authority may be required in respect of body parts has not been tested in the courts.

**Underlying principles**

**Import**

20. The HTA recognises the long established practices involved in the import and export of human tissue and does not wish to inhibit such cross-movement and exchange of material between countries. In addition, the HTA acknowledges that good practice already exists and aims to build upon such practice in this Code.

21. Imported material should be procured, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. In addition, due regard should be given to safety considerations and the dignity and respect accorded to human bodies, body parts and tissue which inform the guidance in all the HTA’s Codes of Practice. It is the responsibility of any individual or organisation wishing to import human bodies, body parts and tissue into England, Wales or Northern Ireland to follow the practical guidance laid out in the Code.

22. All persons or organisations wishing to import human bodies, body parts and tissue into England, Wales and Northern Ireland should be able to demonstrate that the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within those countries, or is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent. They should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service, cost effectiveness, or scientific or research need. Such documentation should be available for inspection by the HTA.

23. The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts and tissue from the living or the

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2 Persons or organisations considering the importation of bodies, body parts or tissues from other countries should take into account the Declaration of Helsinki which reinforces the consent and ethics issues set out in this Code.

3 The Scottish 2006 Act describes consent as ‘authorisation’.
deceased, for the purposes specified in the HT Act\(^4\). The consent provisions of the HT Act do not apply, however, if the material has been imported. Nonetheless, the HTA considers it good practice to ensure mechanisms are in place in the source country for obtaining consent for the reasons outlined in the paragraphs below.

24. All sectors are dependent upon the goodwill and voluntary donation of relevant material from donors to continue their business, practice or research. It is therefore important that public confidence is maintained by standards of good practice. By engaging donor trust and commitment through obtaining consent, the risk of nefarious trading and physical harm in the case of transplantable tissue for human application would also be mitigated.

25. As good practice, importers should therefore satisfy themselves that, in the countries from which they seek to import tissue, the gaining of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained. This involves ensuring that procedures are in place giving the necessary assurances. Best practice guidelines on seeking consent in the UK may be referenced in the HTA’s [code of practice on consent](#).

26. The HT Act makes it clear that bodies and relevant material are not to be exported and then re-imported simply to avoid the Act’s consent requirements.

### Export

27. Exported material should be procured, used, handled, stored, transported and disposed, in accordance with the consent which has been given, with due regard for safety considerations and with the dignity and respect accorded to human bodies, body parts and tissue in codes in England, Wales and Northern Ireland. This includes providing donors with adequate information upon taking consent, that their samples may be transported as exported samples for use abroad.

28. It is the responsibility of the recipient country to ensure that, prior to export, the material is handled appropriately and that the required standards of that country have been met.

### Part 1 - Guidance for HTA-licensed establishments

### Import

\(^4\) If relevant material comes from a living individual, the HT Act does not require consent for those purposes listed in Part 2 of Schedule 1 or for ethically approved material which has been de-identified.
29. Tissue may be imported for use in research projects. A licence may not be needed to store this material in some cases where it is being kept for use in a research project that has been approved by a research ethics authority under the appropriate Regulations. The HTA recommends that, wherever possible, the import and export of tissue is conducted via the HTA licensing regime, which involves a Designated Individual (DI) ensuring that premises are suitable for activities as authorised by the licence.

30. Licensed establishments wishing to import human bodies, body parts and tissue from other countries into England, Wales and Northern Ireland should ensure that they follow the steps set out in the paragraphs below. The DI is responsible for ensuring that suitable practices take place in licensed establishments and should establish systems to fulfil the requirements of this Code. The DI acts as ‘gatekeeper’ for any imported tissue and should ensure that a Service Level Agreement (SLA) or Material Transfer Agreement (MTA) is in place with the end user, confirming the requirements, processes and systems that should be in place, as detailed below.

Consent

31. Good practice requires that effective and reliable processes should be in place for acquiring evidence of informed consent from the prospective donor. This means that the importer should have in place, policies and/or Standard Operating Procedures (SOPs) which clearly set out the evidence indicating how informed consent was obtained, including safeguarding the confidentiality of all information relating to consent. If a third party is importing the material, a SLA should be in place demonstrating that there is a record of consent in a suitable format.

Ethical Approval

32. Importers should satisfy themselves, with due assurance from their collaborators abroad, that any material intended for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. When an establishment imports material into England, Wales and Northern Ireland for research, it is good practice for approval to be obtained from a research ethics authority or the local equivalent in the source country.

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5 The Human Tissue Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 provides further detail on the definition of a research ethics authority. This means any NHS REC in England, Wales or Northern Ireland, together with any other ethics committee recognised by UKECA.
beforehand\(^6\). Many countries have *research* ethics arrangements which operate to agreed standards. The ethical review in the source country may, in some cases, be considered to provide suitable assurances for the importing of material into England, Wales and Northern Ireland.

33. If the importer of the material cannot ensure that ethical standards have been put in place, the risks of accepting such material should be carefully reviewed.

**Governance and quality**

34. The level to which importers might be expected to follow the guidance laid out in this section will be related to the use to which the material will be put. For example, materials for *research* into infectious diseases may actually need infectious agents to be present in the material. The testing of imported *tissue* should meet the same criteria as are applicable at the time for *tissue* sourced elsewhere within England, Wales or Northern Ireland. This includes the testing regimes and the range of testing done.

35. The DI should put in place the following:

1. A quality management system which includes appropriate SOPs for those in the importing department and information on the final destination of the human bodies, body parts and tissue.
2. A coding and recording system which records the reason why the decision was made to import the material and ensures that a robust audit trail is maintained. The audit trail should include details of when the imported material was acquired and where from, the uses to which it was put, when the material was transferred elsewhere and to whom. All relevant details should be recorded in an appropriate register by the person undertaking the import or export of the relevant material. The register should be retained in a safe place and made available for inspection by the HTA on request.
3. A system which ensures that the traceability of *tissue* is maintained during transport and delivery – records should be kept to cover details of: transport and delivery; material transfer agreements with recipients of tissue; SLAs with courier or transport companies. The traceability system should follow the operation of a donor ID system which assigns a unique code to each sample and to each of the products associated with it. All such documentation should be available for inspection by the HTA. When human bodies, body parts and tissue are carried by post or courier, the

\(^6\) Ethical approval is not a requirement for routine clinical practices; the remit of ethical review committees is to consider *research* proposals rather than standard operational procedures in healthcare. Please refer to the [HRA](#) website for further information.
packaging should conform to the international standards for the transport of hazardous clinical material. Detailed requirements for the carriage of ‘Dangerous Goods’ are set out in the Technical Instructions approved and published by the International Civil Aviation Organisation (ICAO).

4. A risk assessment system which ensures that adverse events, reactions, and / or incidents involving imported tissue are investigated.

Disposal

36. A clear policy should be in place for disposing of imported material in a sensitive manner. The disposal arrangements should meet the requirements of the HT Act and the HTA’s code of practice on disposal of human tissue as though the material had been sourced from England, Wales and Northern Ireland.

37. If any specific requests were made by the deceased regarding disposal when consent was obtained abroad, such requests must be carried out. This may include, for example, the return of material to the country of origin.

Documentation

38. The supplier’s record and other documentation of each consignment of imported human bodies, body parts and tissue should be retained by the person undertaking the export for at least five years after disposal of the last part included in the consignment. The register maintained by the person undertaking the import should similarly be retained for at least five years after disposal of the last body part recorded in it. The HTA’s code of practice on disposal of human tissue sets out good practice for the disposal of tissue blocks and slides.

Export

39. SLAs should be in place to ensure that human bodies, body parts and tissue to be exported from England, Wales and Northern Ireland are used in accordance with the consent which has been obtained. Material should be handled, stored, transported and disposed, in a manner consistent with safety considerations, and with the dignity and respect accorded to human bodies, body parts and tissue in legislation and codes in England, Wales and Northern Ireland.

Part 2 - Guidance for those not undertaking licensable activities

Import
40. Although the consent requirements of the HT Act do not apply to imported tissue, nonetheless the HTA considers it good practice for mechanisms to be in place which provide assurance that human material is imported with appropriate consent. Importers not undertaking licensable activities under the HT Act, but who wish to import human bodies, body parts and tissue from abroad into England, Wales and Northern Ireland, should observe the principles set out in the following section as good practice.

**Consent**

41. Good practice requires that consent should be in place before any tissue is accepted for import. This may be of particular importance when supplying material to licensed establishments which will be adhering to consent requirements. This means that effective and reliable processes should be in place for acquiring evidence of informed consent from the prospective donor.

**Ethical approval**

42. It is good practice for importers to satisfy themselves, with due assurance from their collaborators abroad, that any material intended for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. When an individual, establishment or organisation imports material into England, Wales and Northern Ireland for research, it is good practice for approval to be obtained from a research ethics authority or the local equivalent in the source country beforehand. Many countries have research ethics arrangements which operate to agreed standards. The ethical review in the source country may, in some cases, be considered to provide suitable assurances for the importing of material into England, Wales and Northern Ireland.

43. If the importer of the material cannot ensure that ethical standards have been put in place, the risks of accepting such material should be carefully reviewed.

**Quality and safety**

44. Where there is a risk of transmitting infection via imported material, all those planning to import human bodies, body parts or tissue to England, Wales and Northern Ireland should be satisfied that the risks of infection presented are proportionate to the purposes for which they will use the material.

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7 Ethical approval is not a requirement for routine clinical practices; the remit of ethical review committees is to consider research proposals rather than standard operational procedures in healthcare. Please refer to the HRA website for further information.
45. Potential importers should be prepared to provide adequate assurances that appropriate systems are in place to handle and contain the material in a way that protects all persons coming into contact (in the chain of supply and use) with the material from the presence of any infectious agent.

46. Each receiving establishment or organisation should be operated in a manner to minimise risks to the health and safety of employees, donors, volunteers and patients. Suitable premises, environment, and equipment should be available to maintain safe operations.

47. The import or export of all tissues should be handled with caution as all can transmit disease. For example, brains, brain tissue, spinal cord and cerebrospinal fluid, (fresh, fixed or frozen), carry the risk of spreading infectious diseases. Importers should be able to demonstrate expertise that satisfies the Health and Safety Executive in handling these materials, in assessing the likely risks of infection and in containing the material before transporting the materials.

48. Where the material is being moved by or on behalf of an organisation, commercial or public, the organisation should equally be capable of demonstrating its means of assessing and containing risk and of the robustness of its governance arrangements relating to this activity. Organisations which have any doubts about their ability to comply with the Code in these respects should seek advice from the Health and Safety Executive prior to embarking on transportation of the materials.

49. Detailed requirements for the carriage of ‘Dangerous Goods’ are set out in the Technical Instructions approved and published by the International Civil Aviation Organisation (ICAO).

Disposal

50. A clear policy should be in place for disposing of imported material in a sensitive manner. Good practice for disposal arrangements is laid out in the HTA’s code of practice on disposal of human tissue.

51. If any specific requests were made by the deceased regarding disposal when consent was obtained abroad, such requests should be carried out. This may include, for example, the return of material to the country of origin.
Documentation

52. All relevant details of imported and exported bodies, body parts and human bodies, body parts and tissue should be recorded in an appropriate register by the person undertaking the import or export of the relevant material. The register should be retained in a safe place.

53. The supplier’s record and other documentation of each consignment of imported human bodies, body parts and tissue should be retained by the person undertaking the export, for at least five years after disposal of the last part included in the consignment. The register maintained by the person undertaking the import should similarly be retained for at least five years after disposal of the last body part recorded in it.

Export

54. Human bodies, body parts and tissue to be exported from England, Wales and Northern Ireland should be used in accordance with the consent which has been obtained.

Using and adopting existing standards

55. Individuals or organisations involved in the import and export of human bodies, body parts and tissue may already be following good practice set out in voluntary accreditation frameworks covering key issues such as consent, safety, storage and record keeping. The HTA intends that the guidance set out in this Code should complement the guidance laid out in such accreditation systems.

56. Imports and exports of human tissue must normally be declared to HM Revenue and Customs.

Glossary

These terms have been defined with reference to the Human Tissue Act and the HTA’s Codes of Practice and should be read in that context.

Biopsy: a procedure where tissue is removed from a living body for examination under a microscope.

Cells: individual human cells or a collection of human cells when not bound by any form of connective tissue.
**Designated Individual:** means the individual designated in the HTA licence as the person under whose supervision the licensed activity is authorised to be carried on. This person is responsible for securing that other persons to whom the licence applies are suitable persons, that suitable practices are carried out in the course of carrying-on the licensed activity and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of this person.

**Diagnosis:** a process where a disease is identified by signs and symptoms, a history and laboratory tests.

**Donation:** the act of donating human tissue, cells or organs for a Scheduled Purpose.

**Donor:** every human source, whether living or deceased, of human tissue, cells or organs.

**Embryo:** a live human embryo where fertilisation is complete and includes an egg in the process of fertilisation. Ethical approval: defined under Regulations made under Section 1(9) of the Act to mean approval given by a research ethics authority. This means any NHS REC in England, Wales or Northern Ireland, together with any other ethics committee recognised by UKECA.

**Export:** according to the HT Act means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

**Gamete:** live human gametes, eggs or sperm, excluding eggs in the process of fertilisation.

**Human application:** in relation to tissue or cells, means use on or in a human recipient, including use in extracorporeal applications

**Import:** according to the HT Act means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

**Licensing:** a number of activities can only be carried out where the establishment is licensed under the HT Act by the HTA for that purpose. The activities are: the carrying out of an anatomical examination, the making of a post-mortem examination; the removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplant; the storage of an anatomical specimen; the storage (other than of an anatomical specimen) of the body of a deceased person or relevant material which has come from a human body for use for a Scheduled Purpose; and the use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.
Preservation: the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues.

Processing: all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.

Procurement: a process by which tissues or cells are made available.

Quality assurance: a programme for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

Relevant material: is defined by the HT Act as material other than gametes, which consists of or includes human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person.

Research: is concerned with creating new knowledge by addressing clearly defined questions with systematic and rigorous methods. It is about testing innovations or discovering the right thing to do e.g. finding out whether new treatments work and whether certain treatments or models of service delivery work better than others. Research forms the basis of nationally agreed clinical guidelines and standards and is designed to establish best practice.

Research Ethics Committee: an ethics committee established or person appointed to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body.

Scheduled Purposes: the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the HT Act that require consent. The Purposes are divided into 2 parts:

Part 1: Purposes requiring consent: general

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation
Part 2: Purposes requiring consent: Deceased persons

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

**Storage:** maintaining the tissue under appropriate controlled conditions.

**Tissue:** any and all constituent part(s) of the human body formed by cells.