



## **DRAFT**

### **Code of Practice on the import and export of human bodies, body parts and tissue**

#### **Introduction**

1. The Human Tissue Act 2004 (HT Act) sets out a legal framework for the storage and use of tissue from the living and for the removal, storage and use of tissue and organs from the dead.
2. The HT Act repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.
3. The HT Act also establishes the Human Tissue Authority (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue for Scheduled Purposes. The HTA is the UK Competent Authority for the purposes of the EU Tissues and Cells Directive (EUTCD).
4. One of the HTA's statutory functions is to issue Codes of Practice. The HTA has already prepared Codes dealing with:
  - Consent;
  - Donation of organs, tissue and cells for transplantation;
  - Post mortem examination;
  - Anatomical examination;
  - Removal, storage and disposal of human organs and tissue;
  - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation;
  - Public display;

and this Code of Practice on the import and export of human bodies, body parts and tissue should be regarded as complementary.

5. These Codes of Practice give guidance to those carrying out activities which lie within the HTA's remit – including the import and export of human bodies, body parts and tissue – 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.

6. Although Scotland has its separate legislation – the Human Tissue (Scotland) Act 2006 – the HTA has agreed with the Scottish Executive that the guidance as set out in this Code will also apply to Scotland.
7. The terms ‘tissue’, ‘organ’, ‘part organ’, ‘material’, ‘body parts’ or ‘cells’ in this Code come within the meaning of ‘relevant material’ in the HT Act. For definitions of terms used, please refer to the glossary at the back of this Code.

## **Background to the Code of Practice**

8. Human bodies, body parts and tissue have been imported into England, Wales and Northern Ireland for a number of years, for use primarily in medical education and training, and research. Prior to the Human Tissue Act 2004, this practice was not covered by statute<sup>1</sup> and no restriction was imposed on bringing human bodies, body parts and tissue into England, Wales and Northern Ireland.
9. The Department of Health published interim guidance in April 2003 whilst the law was reviewed. That guidance was introduced on the recommendation of the Chief Medical Officer pending implementation of the Human Tissue Act 2004. It dealt with the procurement, handling, recording and disposal of imports and exports of human bodies, body parts and tissue for teaching, research, education or other non-therapeutic purposes. This HTA Code is broader in scope, covering tissue for human application as well.

## **Scope of the Code**

10. The remit of the HTA within the HT Act provides the statutory basis for the HTA to prepare a Code on “the import, and the export, of – (i) the body of a deceased person, or (ii) relevant material which has come from a human body.”
11. The import and export of relevant material is not a licensable activity under the HT Act. However, the storage and use to which the material is put once it is imported may be licensable, if this is for a Scheduled Purpose.
12. This Code provides practical steps for establishments both licensed under the HT Act (see Part 1) and 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 a number of other purposes. The Code also covers existing standards which individuals and organisations involved

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<sup>1</sup> Neither the Anatomy Act 1984 nor the Human Tissue Act 1961 covered the importation of human bodies, body parts and tissue.

in the practice of import and export may already be following (see Part 3) – the HTA intends that the guidance laid out in Parts 1 and 2 should complement these standards, where relevant.

13. This Code applies to the import and export both of:

- (i) human bodies or body parts removed after death and
- (ii) tissue removed at biopsy and during surgery.

From the deceased, this includes material that is fresh, frozen, plastinated, dried, embalmed or preserved in some way (and this will include dry bones and skeletons). From living people, for example for biopsy or research, this includes tissue for research (including paraffin blocks and slides).

14. The geographical scope of “import” and “export” according to the HT Act are as follows:

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

15. 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:

- come under the jurisdiction of the Coroner<sup>2</sup> in England, Wales and Northern Ireland;
- are being brought into, or removed from, England, Wales and Northern Ireland for lawful disposal here or abroad<sup>3</sup>;
- are historical human remains, or human remains incorporated into artefacts, which are more than 100 years old, and imported by museums;
- are from the living and only intended for diagnostic use.

16. If thought necessary, further advice on specific cases may be sought either from the HTA or from the Department of Culture, Media and Sport (DCMS), who in 2004, published Guidance for the Care of

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<sup>2</sup> Or the Procurator Fiscal in Scotland.

<sup>3</sup> There is at present no restriction on bringing bodies or human remains into the UK. However, disposal of such remains by cremation may require authorisation by the coroner in whose district the remains are (in England, Wales and Northern Ireland). 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, case law requires the coroner to hold an inquest, notwithstanding that the death occurred abroad. 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’, 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.

Human Remains in Museums<sup>4</sup>. Their document covers areas of museum activity which may also be affected by the HT Act 2004, although the DCMS guidance has a longer historical reach as it deals with material collected before the period covered by the HT Act.

## **Underlying principles**

### ***Import***

17. The HT Act seeks to ensure that all human bodies, body parts and tissue within the HT Act's scope are treated with appropriate respect and dignity.
18. 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. They should be willing to justify the need for importing, in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service or cost effectiveness.
19. 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 deceased, for the purposes specified in the HT Act<sup>5</sup>. The consent provisions of the HT Act do not apply, however, if the material has been imported.
20. All sectors involved are dependent upon the goodwill and voluntary donation of relevant material from donors to continue their business, practice or research. It is therefore crucial 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. The HTA considers it best practice to ensure mechanisms are in place in the source country for obtaining consent.
21. Importers should therefore satisfy themselves that in any country from which they seek to import tissue, the gaining of consent is a key part in the process by which the material is obtained.
22. Tissue may be imported for use in research projects. A licence may not be needed to store this material providing it is being kept for use in a research project that has been approved by a research ethics authority in England, Wales or Northern Ireland<sup>6</sup>.

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<sup>4</sup> <http://www.culture.gov.uk/NR/rdonlyres/0017476B-3B86-46F3-BAB3-11E5A5F7F0A1/0/GuidanceHumanRemains11Oct.pdf>

<sup>5</sup> 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 or anonymised material.

<sup>6</sup> The Human Tissue Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

23. The HT Act aims to ensure that bodies and relevant material are not exported and then re-imported simply to avoid the consent requirements.

### ***Export***

24. Exported material should be used, handled, stored, transported and disposed of, 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 legislation and codes in England, Wales and Northern Ireland.

## **PART 1**

25. Part 1 of the Code is divided into 2 sections:

Section (i) sets out guidance which all establishments requiring a licence under the HT Act should follow. This includes storing tissue for transplantation (human application).

Section (ii) sets out additional, specific guidance which establishments storing tissue for transplantation (human application) must follow. This is because the EUTCD appropriately imposes additional and more stringent requirements on the import and export of human tissue and cells for transplantation because of the risk of infection.

For the purposes of importing material for human application only, Scotland is also covered.

### **(i) Guidance for licensed establishments, including those storing tissue for transplantation (human application)**

#### **Import**

26. 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 Designated Individual (DI) is responsible for ensuring that suitable practices take place in licensed establishments and should establish systems to fulfil the requirements of this code.

#### **Consent**

27. Effective and reliable processes should have been put in place for acquiring evidence of valid consent. This means that a Standard Operating Procedure (SOP) is in place which clearly sets out the process by which informed consent was obtained. If a third party is importing the material, a Service Level Agreement (SLA) should be in place demonstrating that there is a record of consent in a suitable

format. The establishment should have SOPs in place to ensure the confidentiality of all information relating to consent.

### ***Ethical approval***

28. Importers should satisfy themselves that consent is a key element of an ethical framework in the source country. When an establishment imports material into England, Wales and Northern Ireland for research, approval should be obtained from a research ethics authority or the local equivalent in the country concerned beforehand<sup>7</sup>. Many countries have research ethics committees which operate to international standards. The ethical review in the local country may, in some cases, be considered to provide suitable assurances for the importing of material into England, Wales and Northern Ireland.
29. 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. When an establishment plans to import a significant amount of human bodies, body parts and tissue from a country where no ethical scrutiny is in place, a form of local ethics committee should be set up in the locality concerned to carry out the ethical review role. The HTA endorses this as good practice.

### ***Governance and quality***

30. The level to which importers might be expected to pursue the guidance laid out in this section will be related to the use to which the material will be put. For example, material intended for transplantation (human application) may require extensive testing to demonstrate freedom from infection, whereas materials for research into infectious diseases may actually need infections to be present in the material.
31. The DI should put in place the following systems:
- 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.
  - 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.

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<sup>7</sup> 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.

- A system which ensures that the traceability of tissue is maintained during transport and delivery – records should be kept including details of: transport and delivery; material transfer arrangements 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 donation 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 packaging must conform to the international standards for the transport of hazardous clinical material. The Air Navigation (Dangerous Goods) Regulations 2002 make detailed requirements for the carriage of “dangerous goods” which means any article or substance which is identified as such in the Technical Instructions approved and published by the International Civil Aviation Authority<sup>8</sup>.
- A risk assessment system which ensures that adverse events, reactions, and/or incidents involving imported tissue are investigated.

### ***Disposal***

32. 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, as though the material had been sourced from England, Wales and Northern Ireland.
33. The supplier’s record and other documentation of each consignment of imported human bodies, body parts and tissue should be retained 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. A longer period of retention may be appropriate in many cases, including establishments storing tissue for transplantation (see paragraph 54).
34. 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.

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<sup>8</sup> The Technical Instructions for the Safe Transport of Dangerous Goods by Air are approved and published by the Council of the International Civil Aviation Authority. They are revised from time to time. The current edition is the 2005-2006 English language edition as amended by Addenda to those instructions dated 18 March 2005 and 30 June 2005. This revised edition was incorporated into 2002 Regulations by the Air Navigation (Dangerous Goods) (Amendment) Regulations 2005. The CAA is given enforcement powers, including powers to open, seize and retain packages for the purpose of potential prosecution. Any dangerous goods accident or incident has to be reported to the CAA.

## **Export**

35. 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 of, 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.

### **(ii) Guidance for establishments storing tissue for transplantation (human application) under the EUTCD**

#### **The EUTCD**

36. The HTA, as the UK Competent Authority under the EUTCD, must implement its requirements through Regulations made under the HT Act. The EUTCD is the source of regulation in the area of import and export for establishments storing tissue for transplantation (human application), applying common standards of quality and safety within the Community when tissues and cells (excluding gametes and embryos) move between Member States. The statutory adoption of common standards is intended to reassure the public that tissue and cells procured in other Member States carry the same guarantees as those in their own country.
37. Once fully adopted, the EUTCD will also apply the usual principles of freedom of movement and thus the standards in the EUTCD will apply to import and export involving third countries. This means that, wherever tissues and cells for human application enter or leave the EU, they should have met the standards or equivalent, to those laid down in the EUTCD.
38. The EUTCD contains specific requirements for the import and export of tissue and cells for human application (see parent Directive: Article 9). Implementation of the EUTCD in the UK, under the HTA as the Competent Authority, commenced in April 2006 with the licensing of establishments storing tissue for transplantation. A more comprehensive licensing and regulatory regime under the EUTCD, including provisions covering the import and export of tissue for human application, will come into force in April 2007 once the EUTCD and its technical annexes are transposed into UK law. The HTA may decide to issue a further Code of Practice on its implementation at that point.
39. The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. It ensures that, within the EU, human tissues and cells, whatever their intended use, are of comparable safety and quality even if procured in another Member State, particularly in order to prevent the transmission of diseases and



therefore to protect the health of EU citizens who receive human tissue cells and treatments.

40. This Code draws attention to certain requirements, set out below, for these establishments to follow, in addition to those which are demanded of licensed establishments storing tissue for non-therapeutic use only.

### **Consent**

41. The establishment must satisfy itself, through SLAs with organisations which procure on its behalf and / or SOPs as appropriate, that the following provisions have been fulfilled:

- All necessary information which is required to be given to a prospective donor, or an individual(s) giving consent on behalf of a donor, prior to the donation of human tissues and cells is consistent with the provisions of the HTA Consent and Donation Codes.
- Information is given by trained personnel in a manner and using terms that are easily understood by the prospective donor.
- The information to be provided prior to the donation of human tissues and / or cells must cover at least the purpose and nature of the donation, its consequence and risks, any analytical tests if they are to be performed, the recording and protection of donor data and medical confidentiality, therapeutic purpose and potential benefits of the donation, and information on the applicable safeguards intended to protect the prospective donor.
- The prospective donor must be informed that they have the right to receive the confirmed results of the analytical tests and in a manner and using terms that are easily understood by the donor.
- The prospective donor must be informed of the necessity for obtaining their prior consent in order that the procurement of the human tissues and / or cells is carried out.
- In addition, in the case of deceased donors, the confirmed results of the donor's evaluation (selection / assessment and testing) must be communicated and clearly explained to the individual or individuals giving consent on behalf of the deceased donor.
- In the case of living donors, the healthcare professional responsible for obtaining the medical history or the Accredited Assessor<sup>9</sup> must ensure that the donor has:

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<sup>9</sup> Under the HT Act, donations of bone marrow and peripheral blood stem cells from children who lack the competence to consent and adults who lack the capacity to consent must be assessed by an Accredited Assessor and submitted to the HTA for approval. See the HTA's [Code of Practice on the Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation](#) for further detail.

- (i) understood the information provided;
- (ii) had an opportunity to ask questions and been provided with satisfactory responses;
- (iii) confirmed that all the information provided is true to the best of their knowledge.

***Data protection and confidentiality***

- 42. The establishment should have SOPs to ensure that all information provided in confidence is kept confidential and only disclosed in circumstances permitted by law.
- 43. The establishment should ensure that all data including genetic information collated for any purpose, and to which third parties have access, is rendered anonymous so that neither donors nor recipients remain identifiable.
- 44. The establishment should ensure that the identity of the recipient is not disclosed to the donor or their relatives and vice versa, unless the donor and / or recipient have consented to such disclosure.
- 45. The establishment should have in place a SOP for the control of access to health data and records, including arrangements for:
  - a. Establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to donor files or records, and the transfer of information.
  - b. Establishing and maintaining procedures to resolve all data discrepancies.
  - c. Preventing unauthorised disclosure of information whilst guaranteeing the traceability of donations.
  - d. Considering and responding to applications for access to confidential records and correctly identifying applicants.
  - e. Receiving, checking and arranging authorised access to confidential data and records.
  - f. Notifying the Data Protection Commissioner in accordance with the Data Protection Act, 1988.
  - g. Ensuring that data subjects are aware of their rights under the Data Protection Act, 1988 to access their own health records and correct information held about themselves.

### ***Quality management***

46. The quality management system maintained by the establishment should be put in place and include as a minimum: a quality manual, appropriate SOPs, guidelines, training and reference manuals, reporting forms, donor records and information on the final destination of the imported human tissues and / or cells.
47. The establishment should put in place a SOP to control all records required to provide evidence of conformity to these directions, to the effective operation of the quality management system, and to the conduct of the licensed activity. The SOP should include the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.
48. Records should be kept for a minimum period of 30 years after clinical use or disposal. The records should include the data necessary to ensure that all tissues and cells, procured, processed, stored and / or distributed by the establishment can be traced from the donor to the recipient and vice versa. This traceability should also apply to all relevant data relating to products and materials coming into contact with such tissues and cells.
49. The requirements for procurement and distribution (including packaging, labelling and transportation), processing and storage, and registering and reporting – including recording and notification of serious adverse events and reaction of tissue for human application are laid out very specifically and in detail in the Directions which accompany the EUTCD<sup>10</sup>. Establishments importing material for human application are therefore directed to follow these instructions.

## **PART 2**

### **Guidance for individuals and establishments not undertaking licensable activities under the HT Act**

#### **Import**

50. Individuals and establishments 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.

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<sup>10</sup> [http://www.hta.gov.uk/\\_db/\\_documents/2006-04-25\\_Final\\_Directions\\_given\\_under\\_the\\_HT\\_Act\\_PDF\\_document.pdf](http://www.hta.gov.uk/_db/_documents/2006-04-25_Final_Directions_given_under_the_HT_Act_PDF_document.pdf)

## ***Consent***

51. Prior to the procurement of tissues and cells, an authorised individual from the procuring establishment must confirm and record that a policy or procedure on valid consent for the acquiring and use of imported material has been put in place.

## ***Ethical approval***

52. Before deciding to accept any imported material, potential importers should satisfy themselves as a minimum that consent is a key element of any ethical framework from the source country (subject to the following paragraph).
53. When an individual imports material into England, Wales and Northern Ireland for research, approval should be obtained from a research ethics authority or the local equivalent in the country concerned beforehand<sup>11</sup>. Many countries have research ethics committees which operate to international standards. The ethical review in the local country may, in some cases, be considered to provide suitable assurances for the importing of material into England, Wales and Northern Ireland.
54. 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. When an individual or organisation plans to import a significant amount of human bodies, body parts and tissue from a country where no ethical scrutiny is in place, a form of local ethics committee should be set up in the locality concerned to carry out the ethical review role. This is currently good practice.

## ***Quality and safety***

55. Where there is a risk of transmitting infection via imported material, all individuals or organisations 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.
56. Importing individuals or organisations 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. If there is any doubt about this, advice should be sought from the HTA and/or the Health and Safety Executive.

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<sup>11</sup> 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.

57. As a minimum, each receiving establishment 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 must be available to maintain safe operations.
58. The import or export of brains, brain tissue, spinal cord and cerebrospinal fluid, (fresh, fixed or frozen), should be undertaken with particular caution because of the risks 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.
59. 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.
60. Importers should 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. If there is any doubt about this, advice should be sought from the Health and Safety Executive.
61. When human bodies, body parts and tissue are carried by post or courier, the packaging must conform to the international standards for the transport of hazardous clinical material. The Air Navigation (Dangerous Goods) Regulations 2002 make detailed requirements for the carriage of “dangerous goods” which means any article or substance which is identified as such in the Technical Instructions approved and published by the International Civil Aviation Authority<sup>12</sup>.

### ***Documentation***

62. 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.

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<sup>12</sup> The Technical Instructions for the Safe Transport of Dangerous Goods by Air are approved and published by the Council of the International Civil Aviation Authority. They are revised from time to time. The current edition is the 2005-2006 English language edition as amended by Addenda to those instructions dated 18 March 2005 and 30 June 2005. This revised edition was incorporated into 2002 Regulations by the Air Navigation (Dangerous Goods) (Amendment) Regulations 2005. The CAA is given enforcement powers, including powers to open, seize and retain packages for the purpose of potential prosecution. Any dangerous goods accident or incident has to be reported to the CAA.

63. The supplier's record and other documentation of each consignment of imported human bodies, body parts and tissue should be retained 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. A longer period of record retention may be appropriate in many cases.

## **Export**

64. 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.

## **PART 3**

### **Using and adopting existing standards**

65. 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, as set out in the following paragraphs.
66. Donor informed consent and quality and safety requirements for the international exchange of stem cells and therapeutic lymphocytes are covered in World Marrow Donors Association (WMDA) Standards. WMDA standards are applied throughout Europe (and internationally). WMDA standards provide for the health screening of donors to protect both recipient and long-term donor health. They ensure that the donation procedure will be undertaken only for patients for whom transplantation is a medically acceptable procedure.
67. WMDA standards on data entry and storage ensure the maintenance of accurate records, indicating that accurate records be maintained for an appropriate period of time as dictated by national standards. The standards also indicate that all patient and donor communications and records must be stored to ensure confidentiality and that records must be preserved and protected from accidental or unauthorised access, destruction or modification. Product identification is also covered.
68. The Foundation for the Accreditation of Stem Cell Therapy/Joint Accreditation Committee EBMT-ISCT Europe (FACT/JACIE) guidelines sets standards for quality and safety in all aspects of haemopoietic cell transplantation for therapeutic use. The standards cover the safety of both the donor and the recipient, as well as product safety.

69. The FACT/JACIE standards specify traceability of products through use of unique identifier for every donation. The guidelines refer to Quality Management standards and advise that the programmes should have a written Quality Management Plan in place. These guidelines also refer to establishing an inventory control system, a records management system and an electronic record-keeping system as additional mechanisms of ensuring best practice for documentation. Guidance on record maintenance is also provided.
70. The Medicines and Healthcare products Regulatory Agency (MHRA) has produced a Code of Practice which outlines the principles for assuring the safety and quality of therapeutic products which use material of human origin and which may be produced using tissue engineering practices. The guidance refers to implementing and maintaining a Quality Assurance System, ensuring Quality Control of Materials, Microbiology Safety of Donations, safe Production and Processing Practices, as well as Product Performance.
71. The UK Blood Safety and Quality Regulations (2005) set the standards of quality and safety for the collection, testing, processing, storage and distribution of blood and blood components. The Regulations state (Article 13) that any blood or blood components imported into the UK must meet standards of quality and safety equivalent to those laid down in Part 5 of the Schedule.
72. Imports and exports of human tissue must normally be declared to HM Revenue and Customs. Import and export entries, declarations and related documentation must be retained for a minimum of three years and up to six years. Further advice, if required, can be obtained from the HM Revenue Customs National Advice Service<sup>13</sup>.

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<sup>13</sup> 0845 010 9000.

## 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.

**Anonymisation:** is a procedure to ensure that if relevant material is removed from a human body, all necessary steps are taken to prevent identifying the person from whose body the material has come.

**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 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:** means a live human embryo where fertilisation is complete and includes an egg in the process of fertilisation.

**Ethical approval:** Defined under Regulations<sup>14</sup> made under Section 1(9) of the Act to mean approval given by a research ethics authority.

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

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

**Haemopoietic:** Relating to the production of blood cells.

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<sup>14</sup> The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.



**Human application:** The use of tissue cells on or in a human recipient.

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

**JACIE:** Joint Accreditation Committee – International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation.

**Licensing:** A number of activities can only be carried out where the establishment is licensed under the 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.

**Living donors:** The person donating tissue, cells or organs for transplantation. The most common forms are live kidney donation (where one kidney is removed), or live bone marrow donation.

**Organ:** A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy

**Peripheral blood stem cells:** Cells found in the bloodstream which are able to differentiate into all the cell types found in the blood.

**Post mortem:** Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes. A hospital post mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post mortem examinations are carried out under the authority of the Coroner and without consent to assist Coroners in carrying out their functions.

**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 Act as material other than gametes, which consists of or includes human cells. In the 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:** Scheduled Purposes are the activities relating to the removal, storage and use of human organs and other tissue, listed in Schedule 1 of the 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

**Serious adverse event:** Any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissue and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients, or which might result in, or prolong, hospitalisation or morbidity.

**Stem cell:** A precursor cell that can develop into more than one kind of cell. For example, early bone marrow cells can develop into red blood cells, white blood cells or platelets.

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

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

**Tissue establishment:** A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissue and cells are undertaken. It may also be responsible for procurement or testing of tissue and cells.

**Transplant:** An implant of an organ, tissue or cells either from and into the same body or from one person to another.

**Transplantable material:** Defined under draft Regulations made under Section 34 of the HT Act to mean the whole or part of any of the following organs if it is their function to be used for the same purpose as the entire organ in the human body: kidney, heart, lung or a lung lobe, pancreas, liver, bowel, larynx, face, or limb. Defined in the same Regulations under Section 33 of the Act to mean organs or part of organs if it is their function to be used for the same purpose as the entire organ in the human body, or bone marrow. This definition is subject to change pending finalisation of the Regulations. ('transplantable tissue' used in the code.)

## Background reading

*Learning from Bristol: the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984–1995*, Bristol Royal Infirmary, July 2001.

*Report of the Royal Liverpool Children's Inquiry*, January 2001.

*Department of Health (May 2003) The investigation of events that followed the death of Cyril Mark Isaacs*; Department of Health Isaacs Report Response, July 2003.