HTA
Human Tissue Authority

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Code of Practice – Import and export of human bodies, body parts and tissue

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An independent statutory regulator sponsored by DH Department of Health

Contents

Introduction

1. The Human Tissue Act 2004 sets out a legal framework in England, Wales and Northern Ireland for the storage and use of human tissue from the living and for the removal, storage and use of human tissue and organs from the dead.

2. The Human Tissue Act 2004 (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 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 also the Competent Authority for the purposes of the EU Tissues and Cells Directive (EUTCD) across the UK, including Scotland as well, as formally set out in the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Therefore, Scotland should not be treated as another country for the purposes of importing and exporting tissue for human application under the 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 – this mirrors the HT Act 2004. The HTA expects that the requirements applying to tissue imported from Scotland will be maintained at the level of the rest of the UK. Therefore, in many ways importers will be able to ensure that appropriate consent (or 'authorisation' as it is described in Scotland) has been

obtained, together with assurances that there is an audit trail for the tissue concerned. The use of tissue taken from living people in Scotland for purposes such as research is not covered by the Scottish Act, but will be dealt with in a forthcoming Scottish Health Department Letter. The intention is to align arrangements in Scotland as closely as possible with those established by the HTA for the rest of the UK. The Department of Health has made clear for a number of years that research involving human tissue should have Research Ethics Committee approval, and importers should have no difficulty in meeting the requirements of this Code as regards such tissue.

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. For further detail on the definition of 'human application' refer to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 when published.

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 in research. Prior to the Human Tissue Act 2004, this practice was not covered by statute[1] 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.

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

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 or export, of –

    (i) the body of a deceased person, or
    (ii) relevant material which has come from a human body," for use for a Scheduled Purpose.

11. 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. If material is being imported or exported for human application, under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 this must be carried out under the authority of a licence or a third party agreement with an establishment licensed by the HTA to store material for human application.

12. 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 (see Part 3) – the HTA intends that the guidance laid out in Parts 1 and 2 should complement these standards, where relevant.

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

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

    (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. From living people, this includes tissue for research (including paraffin blocks and slides).

15. The geographical scope of "import" and "export" according to the HT Act is 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.

16. 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:

- fall outside the HT Act e.g. gametes and embryos created outside the human body, and material that does not contain cells;
- come under the jurisdiction of the Coroner[2] in England, Wales and Northern Ireland;
- are being brought into, or removed from, England, Wales and Northern Ireland for lawful disposal here or abroad[3] ;
- 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.

17. 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 Human Remains in Museums[4]. 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.

2 Or the Procurator Fiscal in Scotland.

3 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.

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

Underlying principles

Import

18. 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.

19. 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.

20. All persons or organisations wishing to import human bodies, body parts and tissue into England, Wales and Northern Ireland[5] 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. This process will help importers to 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.

21. The HT Act makes consent[6] 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[7]. 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.

22. 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.

5 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.

6 The Scottish 2006 Act describes consent as 'authorisation'.

7 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 anonymised.

23. 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.

24. 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

25. 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.

26. 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

27. The following guidance in the Code is divided into two parts, covering licensed establishments and then those that do not require a licence.

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

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

    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.

Some guidance in Part 1 is repeated since users may need to refer to both sections (i) and (ii).

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

(i) Generic guidance for HTA licensed establishments, including those storing tissue for transplantation (human application)

Import

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[8]. 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. However, the HTA recognises that in rare circumstances involving tissue for human application, there may be a proven clinical need such that this is not possible and that, as a result, there may be no DI in place to safeguard the processes. In such cases, guidance for direct authorisation by the HTA will be provided on the HTA website.

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

8 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.

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)[9] 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. Although consent is not a formal requirement of the Act for import and export, there are detailed provisions relating to consent under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which establishments storing tissue for human application are required to follow (see paragraph 47).

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 beforehand[10]. 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. When an establishment plans to import a substantial 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 source country concerned, with necessary guidance from their collaborators abroad where appropriate, to carry out the ethical review role. The HTA endorses this as good practice.

9 Researchers may use MTAs, rather than SLAs, for tissue being imported for research purposes

10 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 NRES website – http://www.nres.npsa.nhs.uk for further information. The document 'Governance arrangements for NHS Research Ethics Committees '(GAfREC) published by the Department of Health in July 2001 is available at http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf

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, 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. 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:

- 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.
- 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 packaging should 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[11].

11 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.

- 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 Removal, storage and disposal of human organs and tissue[12], 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. A longer period of retention is required for establishments storing tissue for transplantation (see paragraph 55). The HTA's Code of Practice on Removal, storage and disposal of human organs and tissue, sets out good practice for the disposal of tissue blocks and slides (A37–38).

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.

12 http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_-_Removal.pdf

(ii) Specific guidance for establishments storing tissue for transplantation (human application) under the European Union Tissues and Cells Directive (EUTCD)

The EUTCD

40. 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.

41. It therefore follows that in terms of implementing the EUTCD, tissue for human application from Scotland is not considered to be from another country (see paragraph 6) i.e. not imported, as applies to any country within the EU.

42. 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.

43. The EUTCD contains specific requirements for the import and export of tissue and cells for human application (see parent Directive: Article 9). The HTA, as the UK Competent Authority under the EUTCD, must implement the requirements of the Directives through the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Implementation of the EUTCD in the UK, under the HTA, 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 later this year once the EUTCD and its technical annexes are transposed into UK law.

44. When importing human cells and/or tissues for donation from Member States, establishments should consider the Directions which accompany the EUTCD[13], which set out specific guidelines which establishments storing material from both living and deceased donors must follow.

45. This Code draws attention to certain requirements, set out below, for these establishments to follow; these are in addition to those which are demanded of licensed establishments storing tissue for non-therapeutic use only. These additional requirements imposed on establishments importing material for human application are drawn from the Directions which accompany the EUTCD. These are

13 http://www.hta.gov.uk/_db/_documents/2006-04-25_Final_Directions_given_under_the_HT_Act_PDF_document.pdf

Directions issued by the Authority, as the Competent Authority, under the Directive Regulations.

Licensing

46. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, a licence is required to import or export tissues or cells intended for human application. A licence is not required if the establishment has a third party agreement with an establishment which is licensed to store tissues and cells for human application. HTA Directions set out the standards that establishments will need to meet under the EUTCD, and these will be made available on the HTA website shortly.

The following sections refer to additional requirements which establishment storing tissue for human application must follow under the EUTCD.

Consent

47. 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[14] must ensure that the donor has:

(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

48. The establishment should have SOPs to ensure that all information provided in confidence is kept confidential and only disclosed in circumstances permitted by law.

49. 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.

50. 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.

51. 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.

52. It will be important for establishments to comply with any further confidentiality requirements which will be detailed in due course in the final version of the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

14 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.

Quality management

53. The establishment should put in place a quality management system which should 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.

54. The establishment should put in place a SOP to control all records to provide evidence of the effective operation of the quality management system and the conduct of the licensed activity. The SOP should include the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.

55. Records should be kept for a minimum period of 30 years after clinical use or disposal of tissues or cells. 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.

56. 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. Establishments importing material for human application are therefore directed to follow these instructions.

Part 2

Guidance for individuals, establishments and organisations not undertaking licensable activities under the HT Act

Import

57. 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

58. Good practice requires that a minimum level of 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. Prior to the procurement of tissues and cells, an authorised individual from the procuring establishment should ensure that policies and/or Standard Operating Procedures (SOPs) are in place 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 Service Level Agreement (SLA) should be in place demonstrating that there is a record of consent in a suitable format.

Ethical approval

59. 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[15]. 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.

15 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 NRES website – http://www.nres.npsa.nhs.uk for further information. The document 'Governance arrangements for NHS Research Ethics Committees '(GAfREC) published by the Department of Health in July 2001 is available at http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf

60. 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 planning to import a substantial 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 source country, with necessary guidance from their collaborators abroad where appropriate, to carry out the ethical review role. The HTA endorses this as good practice.

Quality and safety

61. 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.

62. 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. If there is any doubt about this, advice should be sought from the HTA and / or the Health and Safety Executive[16].

63. 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.

64. 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.

65. 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.

16 http://www.hse.gov.uk/pubns/indg136.pdf

66. When human bodies, body parts and tissue are carried by post or courier, the packaging should 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[17].

Disposal

67. 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 Removal, storage and disposal of human organs and tissue[18].

68. 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

69. 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.

70. 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. A longer period of retention is required for establishments storing tissue for transplantation (see paragraph 55). The HTA's Code of Practice on Removal, storage and disposal of human organs and tissue, sets out good practice for the disposal of tissue blocks and slides (A37–38).

Export

71. 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.

17 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.

18 http://www.hta.gov.uk/_db/_documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_–_Removal.pdf

Part 3

Using and adopting existing standards

72. 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.

73. Donor informed consent and quality and safety requirements for the international exchange of stem cells and therapeutic lymphocytes are covered by World Marrow Donors Association (WMDA) Standards. WMDA standards are applied 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. The Council of Europe has produced a 'Guide to safety and quality assurance for organs, tissues and cells'[19] which sets out guidance on the standards required and the quality assurance that should be achieved in services for the transplantation of human organs, tissues and cells in Member States. The Guide includes safety and quality assurance standards for procurement, preservation, processing and distribution for organs, tissues and cells of human origin (allogeneic and autologous) used for transplantation purposes.

79. The European Human Tumor Frozen Tissue Bank[20] (Tubafrost) based in Holland runs a collaborative tissue bank involving several European countries. They have considered the issues surrounding the transfer of tissue between countries and their solutions may be considered by users to be a practical guide to follow in addition with the HTA's guidance laid out in this Code.

80. 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 can be obtained from the HM Revenue Customs National Advice Service[21].

19 https://www.anvisa.gov.br/sangue/simbravisa/Guia%20de%20Seguran%E7a%20e%20Qualidade%20para%20%20tecidos%20orgaos%20e%20celulas%20Uniao%20Europeia.pdf

20 http://www.tubafrost.org

21 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 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[22] 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.

FACT: Foundation for the Accreditation of Cellular Therapy

Gamete: live human gametes, eggs or sperm, excluding eggs in the process of fertilisation. Haemopoietic: relating to the production of blood cells.

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.

22 The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

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 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.

Living donor: 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 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

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 HT 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.