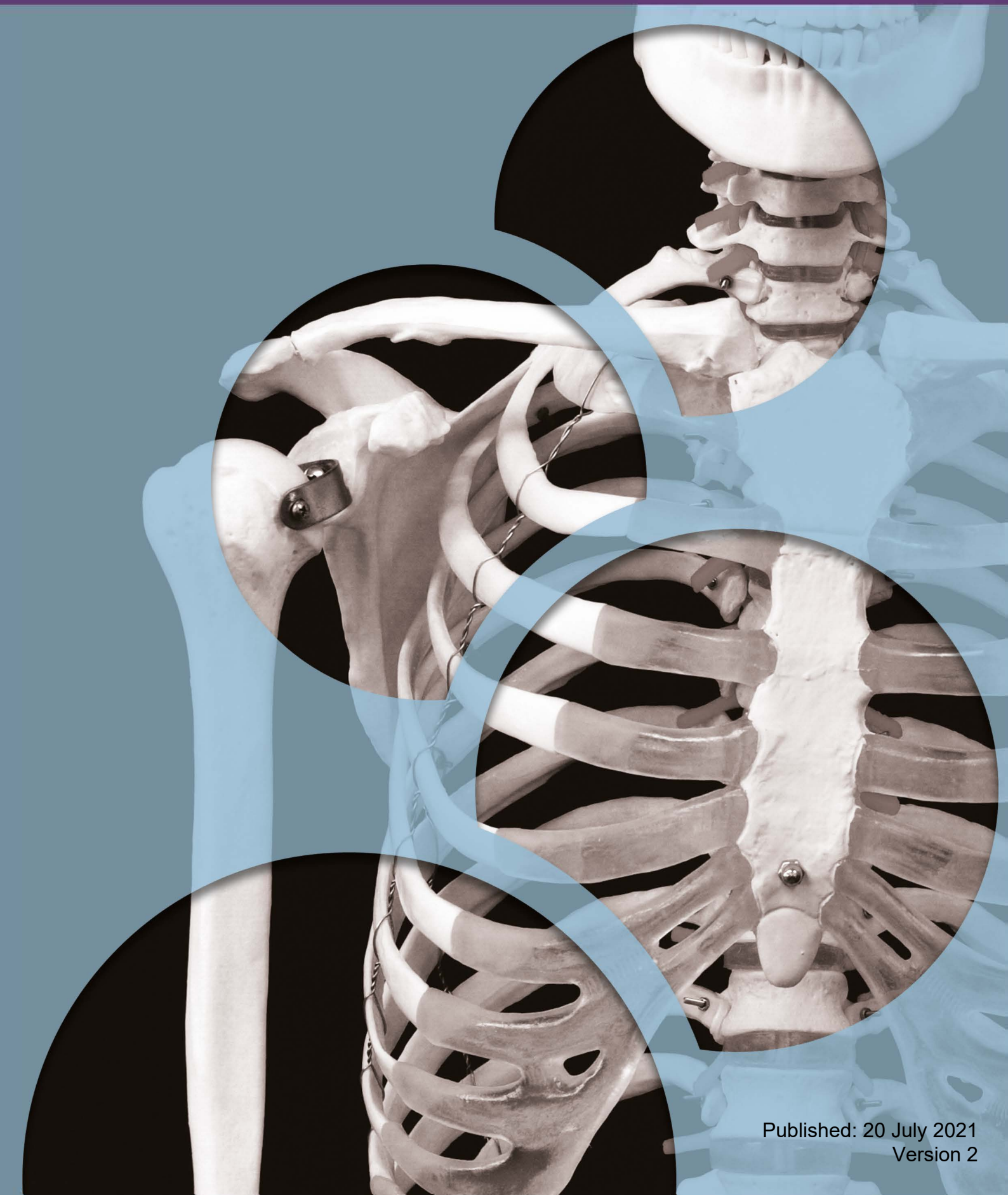
D Public Display

HTA
Human Tissue Authority

Code of Practice and Standards



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Code D: Public Display

Contents

Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:

    a. post-mortem examination;
    b. anatomical examination;
    c. public display of tissue from the deceased; and
    d. the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.

3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.

4. This document is part of a suite of seven Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA's remit under the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.

5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA's remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.

6. HTA Code A: Guiding principles and the fundamental principle of consent contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:

    a. consent;
    b. dignity;
    c. quality; and
    d. honesty and openness.

7. For the public display sector, this means that bodies of the deceased, body parts or other human specimens should be treated with respect in an environment that is safe and secure; that the dignity of the deceased should be maintained at all times whilst they are being stored or are on display; and that their display is in line with the consent given. For specimens that are imported, it means that the country of origin should have a legal and ethical framework which includes consent and protects the interests of the deceased and their families.

8. In combination, Code A and this Code aim to provide anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

Introduction to the Public Display Code

9. The display of human bodies and tissue of human origin is not new to the United Kingdom (UK), but it has primarily been carried out by establishments involved in medical education and training and public museums. The HT Act makes consent a legal requirement for the storage and display of human material where it is less than 100 years since the person's death. It also makes these activities subject to licensing by the HTA, where the material is from the body of a deceased person. This Code explains the consent and licensing requirements of the HT Act as they apply to public display, and includes practical advice to those involved in the public display of human material, whether on a permanent or temporary basis.

10. Although advice and guidance on the care and display of human remains has been available from the Department for Culture, Media and Sport (DCMS) since 2005, the activity of public display was not covered by statute before the HT Act. Prior to this, there was no restriction on the display of human bodies or material of human origin (referred to in the HT Act as relevant material).

11. A key principle of the HT Act is that all human bodies and materials of human origin within its scope should be treated with respect and dignity. In relation to the public display of human material, this principle applies both to those showing the material, and to those viewing it.

12. Ethical issues raised by the display of human materials are explored in DCMS Guidance for the care of human remains in museums, which should be read by anyone involved in the display of human material. This acknowledges their unique status within museum collections and the special responsibilities placed on those who acquire and display them. The DCMS guidance has a longer historical reach, dealing with material collected before the period covered by the HT Act. However, the DCMS guidance covers some areas of museum activity which are also affected by the HT Act, and the HTA advises anyone involved in the display of human material to refer to this guidance.

13. HTA-licensed establishments in the public display sector form a diverse group. This includes:

    a. national museums that maintain largely static, permanent collections;
    b. a charitable foundation dedicated to achieving improvements in human and animal health; and
    c. small specialist museums and organisations that stage temporary exhibitions.

14. The public display of human material and public engagement with human specimens in the areas of medicine and the humanities are becoming increasingly popular. As the interest of the public grows, museums are finding new roles for their collections and exploring novel ways of engaging with the

public. This Code seeks to ensure that all those involved in activities that involve the public display of human material are aware of the statutory and regulatory requirements, as well as the guiding principles of consent, dignity, quality and honesty and openness, which should underpin the conduct of these activities.

15. The HTA recognises that many museums holding permanent collections are accredited under the Arts Council England's Museum Accreditation Scheme. These establishments must make sure that they meet all relevant legal, ethical and safety requirements, and have well established collections management procedures. The Accreditation Scheme includes standards on care and conservation, which satisfy many of the HTA's requirements relating to the public display of human material. These establishments are also subject to the Museum Association's code of ethics and associated guidance.

Scope of this Code

16. Under the HT Act, public display of the body of a deceased person and relevant material from a living or a deceased person is a scheduled purpose for which consent is required. In some cases, it is also a licensable activity. Detailed information about scheduled purposes and licensable activities is explained in Annexes B and C.

17. The HT Act does not contain a definition of public display. The HTA considers public display to be 'an exhibition or display in which the body of a person, or relevant material which has come from the body of a person, is used for the purpose of being exposed to view by the public'.

18. Public display may mean many things and the Code includes examples which illustrate situations that are, or are not, considered to be display to the public. In broad terms, it should be taken to mean events that are open to the public, whether by ticket sale or free access, regardless of the location and purpose of the venue and whether temporary or permanent. It includes static installations or exhibitions, as well as performance art or theatrical productions.

19. The HT Act includes hair and nails from the body of a deceased person within the scope of its definition of relevant material. Human material that has been modified in some way, or that is bound up with non-human materials, is also within scope, as are human body fluids or soft tissue used, for example, in the creation of an art work. This includes human cells used in the making of 'bioart'.

20. Throughout this guidance, examples are given to help establishments determine whether or not their activities fall within the remit of the HTA.

21. The legal requirements of the HT Act and the guidance given in this Code do not apply in the case of bodies or relevant material where:

a. the person died before the HT Act came into force on 1 September 2006; and
b. at least 100 years have elapsed since the date of the person's death.

22. Nor do they apply to display for the purposes of:

a. enabling people to pay their final respects to the deceased;
b. display which is incidental to the deceased's funeral; or
c. the display of bodies or relevant material displayed in a place of public religious worship and used for the purposes of religious worship or contemplation.

23. The display of photographic or electronic images falls outside the scope of the HT Act. Therefore, this Code does not apply to broadcast or printed images. The HTA endorses the guidance on images provided by the General Medical Council (GMC). Further guidance on images is provided in paragraphs 58-60.

24. The HT Act provides for a number of specific museums to transfer from their collections any human remains that they reasonably believe to be the remains of a person who died less than one thousand years before section 47 the HT Act commenced on 3 October 2005. Section 47 is in Part 3 of the HT Act and is headed 'Power to de-accession human remains'. However, the HTA has no regulatory remit in relation to this power.

Offences under the HT Act

25. The HT Act sets out a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the Public Display sector, the offences are as set out below.

26. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.

27. Section 16(1) and (2) of the HT Act prohibit (amongst others) the following activities, except under the authority of a licence:

a. the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes; and
b. the use of the body of a deceased person or relevant material which has come from the body of a deceased person for the purpose of public display.

28. To undertake an activity listed in section 16(2) without the authority of a licence from the HTA is an offence under section 25(1). A person does not commit an offence if they reasonably believe the activity they are carrying out is not licensable, or that they are acting under the authority of a licence.

29. It is not an offence to display relevant material from a living person on unlicensed premises, even if the person has since died.

30. In addition, it is not an offence to sell material of human origin, unless, in doing so, relevant material from the body of a deceased person is on view to the public on unlicensed premises.

31. Finally, it is not an offence to exhibit or broadcast images of the body of a deceased person or relevant material from the deceased.

Structure and navigation

32. The main body of the Code is divided into two main sections: consent and licensing. In each section, the requirements of the HT Act and any exemptions are explained. There follow separate sections on particular issues relating to the public display of human material, such as the import and disposal of material.

33. Annex B explains the difference between licensable activities and scheduled purposes. This distinction has sometimes caused confusion.

34. Annex C provides flowcharts which summarise the licensing and consent requirements for public display of human tissue from the living and the deceased.

35. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA's website.

Consent

36. The HT Act and common law make consent a legal requirement for the removal, storage and use of relevant material which has come from a human body for scheduled purposes. Scheduled purposes are listed in Schedule 1 of

the Human Tissue Act and include public display. Therefore, anyone removing, storing or using material for the purpose of public display, whether from a deceased person or from a living person, must be satisfied that consent is in place.

37. The consent requirements of the HT Act are not retrospective. This means that establishments do not need to obtain consent for the storage or public display of bodies or relevant material that were already in their possession at the time the HT Act came into force on 1 September 2006. Material held before this date is referred to as existing holdings.

Example

A surgeon has a private collection of preserved human body parts and tissue thought to have come from the body of a deceased person, which she acquired early in her career and uses for teaching medical students. On retirement, she offers the specimens to a museum for public display. The museum has concerns that consent may not have been obtained appropriately for all specimens. As the consent requirements of the HT Act are not retrospective, the specimens can be treated as existing holdings and consent is not required for their display. However, an HTA public display licence is required if the material came from people who died less than 100 years ago.

38. Where the person has died, consent must have been given by them in life for storage for public display or actual public display of their body, body parts or tissue after death (whether an adult or a child). Their consent must be written and (i) signed by the person concerned in the presence of at least one witness who attests the signature, or (ii) signed at their direction in their presence and the presence of at least one witness who attests the signature. Alternatively, it can be stated in an adult's legally made will. Neither the relatives nor any other person can consent to the use of an individual's body after their death for public display. This applies whether the person is an adult or a child.

39. Anyone organising a public display of bodies or relevant material that are not existing holdings must have the necessary assurance that valid consent has been given. They do not need to have taken or recorded the consent personally.

40. Although the displaying of photographic or electronic images falls outside the scope of the HT Act, the HTA believes that it is good practice for consent to be obtained for the making and subsequent display of such images.

Licensing

41. Licensing is one of the regulatory functions of the HTA. The HT Act lists among its licensable activities the storage and 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. Therefore, a licence is required for the public display of bodies or relevant material from the deceased, but not from the living.

42. In considering whether to issue a licence for the public display of human material, the HTA will seek assurance that licensing Standards are met by the establishment (see paragraphs 75-79). This will include ensuring that it has a clear policy on the behaviours, actions and attitudes demonstrated by staff and visitors, whether or not directed at the exhibits, that might be considered to disregard the dignity of the deceased.

Example

An art gallery is staging an exhibition, which includes plastinated bodies in a variety of poses demonstrating the anatomy of the human body. The gallery usually offers its exhibition space as a venue for private functions such as birthday parties and wedding receptions. Reflecting its policy on the display of human material, it decides not to offer this service for the duration of the exhibition, out of respect for the deceased.

43. A licence is required regardless of the number of items that are on display and the HTA may take into account the number of items on display when setting licence fees, which are reviewed annually and set out on the HTA's website. A collection of items of the same type and known to have come from a single person can be counted as one item for the purpose of licensing.

Example

A music school displays the preserved hands of the school's founder, a famous pianist. The founder specifically asked for them to go on display in the school before he died in 1948. The music school has no plans to display any other human exhibits but wants to continue to display the hands, in line with the founder's wishes. For the purpose of HTA licensing, the school has one exhibit of human material on public display.

44. The existing holdings exemption to the consent requirements of the HT Act referred to in paragraph 37 does not apply to the licensing requirement. This means that material less than 100 years old that was already in the possession of museums at the time the HT Act came into force on 1 September 2006 is subject to licensing by the HTA.

Example

A museum is displaying a number of human skulls in an exhibition about the history of dentistry. The exhibition has been staged since the early 1970s and no additions have been made to the collection since 1987. Although consent was given for many of the exhibits, there is no legal requirement under the HT Act for it to be in place. However, in accordance with the HT Act, a licence for storage for public display is required.

45. The HTA does not consider the display of bodies or relevant material to small groups of relevant professionals as part of a pre-determined programme of education and training to be public display.

Example

A hospital allows police officers that are dealing with scenes of crime to witness a post-mortem examination as part of their introduction to forensic medicine. The hospital is unsure whether it is required to have an HTA licence for public display. It is advised that a public display licence is not required as training involving the examination of bodies, which is delivered to the police or paramedics as part of their professional development, is not considered public display.

46. The HTA also does not consider the display of bodies or relevant material to students who are embarking on a career in healthcare to be public display. This includes where the students are invited to visit from a different establishment.

Example

Medical students beginning their first year of study are taken on a tour of the anatomy and pathology museum of a teaching hospital licensed by the HTA for anatomical examination. As access to this museum is restricted to practitioners and medical students, the hospital's licences are sufficient and no additional licence is required for public display.

47. Display of bodies, or relevant material from bodies of the deceased, to members of the general public, for whatever reason, is considered to be public display.

Example

At a university open day for the general public, visitors are shown the lungs of a smoker and a non-smoker to demonstrate the effects of smoking. As members of the public are viewing the exhibits, an HTA public display licence is required. The lungs were obtained after death from people who died after 1 September

2006, so written and attested consent for public display is required from the individuals in life in order for the public display to lawfully take place.

48. Any individual or organisation displaying material of human origin should make sure that visitors are aware they will come across human remains, whose display may provoke an emotional or ethical response, particularly in the very young. Giving consideration to the format of the display to ensure that it is appropriate to the material being shown, and does not disregard the dignity of the deceased, may help promote a positive visitor experience.

Example

A city museum and art gallery is mounting an exhibition on death and the human experience. The exhibition is intended to provide an educational experience for visitors; stimulating a discussion on death and increasing their awareness of how individuals and different cultures respond to death. It has a range of artefacts, all less than 100 years old, from different areas of the world, including a human jaw bone incorporated into a necklace from the Andaman Islands which was worn as a sign of mourning, human trophy skulls from Papua New Guinea and a human skull with attached cattle horns from India, believed to prevent the deceased from hearing the voices of their relatives. To ensure that visitors get the most out of their visit to the exhibition and are not alarmed by any of the exhibits, the museum has placed warning signs to alert visitors about the sensitive items on display and provided contextual information about each exhibit. There is also a notice which suggests that the exhibition is suitable for children over 14 years. There is a dedicated seating area which visitors can use for reflection, if the exhibition provokes an emotional response.

49. As noted earlier, storage for the purpose of public display or the actual public display of body parts or tissue from the living do not require licensing. Neither is a licence needed for the continued storage or public display of that material should the person subsequently die.

Example

A human heart is on permanent display in a museum. The heart came from a patient who underwent a successful heart transplant and consented for her diseased heart to be displayed. A licence is not required, and will not be required for the continued display of the heart following the donor's death.

50. Bodies or relevant material from the deceased imported into the UK for public display are subject to licensing by the HTA.

51. The duration of the public display does not affect the requirement for licensing. Establishments that wish to exhibit human material must ensure that they have

the necessary licences in place before they begin to store or exhibit the material.

Example

A temporary exhibit of several preserved human bodies sourced from an establishment in another EU country is displayed in a public museum in order to illustrate the physiology of athletes. The exhibition is for six months and the museum does not display any other human bodies or relevant material. A licence is required from the HTA and the establishment is advised to refer to the advice given in this Code on the import of human material.

52. Some museums hold material with no intention of ever putting it on public display. Instead, they keep it as part of a museum archive of items of historical interest or for ethnographic or anthropological research. In these cases, a licence is not required. If the establishment informs the HTA in writing of its intention never to display the material, the HTA will be satisfied that the retention of this material falls outside its remit.

Material over 100 years old

53. The legislative requirements of the HT Act do not apply to bodies or relevant material if more than 100 years have elapsed since the date of the person's death. Consent is not, therefore, required for the public display of bodies or human material over 100 years old. Nor is a licence required.

54. Some museums hold collections where the age of the material is unknown. This may be because no documentary evidence, such as archival records, receipts or scientific evidence (such as carbon dating) is available. Where investigations are inconclusive and it is uncertain whether the material is over 100 years old or not, the earliest known acquisition date may be taken as an indicator of the age of the material.

55. There may be circumstances where the acquisition date is within the last 100years, but there is good reason to believe that the material is more than 100 years old. In such cases, the HTA will accept a written statement of this from an independent and objective expert in the field. Where no acquisition date is available, an HTA licence should normally be applied for.

Example

A national museum has obtained a large number of preserved human organs from a hospital museum that has closed down. It has records which show that the hospital museum obtained the exhibits in the 1930s and 1940s. However, it

believes that the donors died more than 100 years ago. As there are no records to confirm when the people died, the museum has sought advice from the Professor of Biological Anthropology at a well-respected academic institution. The professor has stated in writing that, in their professional opinion, the specimens are more than 100 years old. The HTA has accepted this as evidence of the age of the specimens and advised that no licence for public display is required.

Loans to other museums

56. The HT Act does not allow the loan of items or collections containing human material within the scope of the HT Act from a licensed establishment to a non-licensed establishment, except in the case of anatomical specimens (see the Code of Practice on Anatomical examination). Where relevant material from a deceased person is to be stored or used in a public display, a licence is required by the establishment on whose premises the material is to be stored or displayed.

57. Where material is moved between licensed establishments, there should be a documented loan agreement, which sets out:

    a. the steps taken to ensure safe handling of the material;
    b. any environmental controls required; and
    c. procedures to deal with adverse events, such as damage to the material or a breach of security.

Photographic/electronic images

58. The display of photographic or electronic images falls outside the scope of the HT Act; therefore, a licence is not required for the public display of photographs containing images of bodies, body parts or other human tissue samples or for electronic images, for example on television.

Example

A small independent gallery is exhibiting the work of a photographic journalist who has spent several years taking photographs of the homeless and dispossessed in major cities around the UK. These include a small number of images of the bodies of homeless people who have died whilst living on the streets. The exhibition is not subject to licensing by the HTA and the consent provisions do not apply to the display of these images.

Example

A television production company plans to film a group of schoolchildren observing the dissection of a human body for a documentary on human anatomy. The filming of the programme and its subsequent broadcast on television are outside the remit of the HTA. However, the real time viewing of the dissection by the schoolchildren is considered by the HTA to be a public display and a licence is required. In addition, the television production company is advised that as the body will be that of a person who died after the commencement of the HT Act, consent for their body to be used for public display will have to have been given by the person before they died.

59. If filming takes place on premises licensed by the HTA, the anonymity of subjects should be preserved. The number of people present at the filming should be kept to a minimum to ensure, as far as possible, the dignity of the deceased. The Coroner should be informed and their agreement sought if any bodies being filmed are under coronial jurisdiction.

60. The Designated Individual (DI) of the licensed establishment has a statutory duty to ensure that suitable practices take place on the premises. This includes ensuring that the bodies in their care are treated with dignity and respect. This responsibility must be understood and given due regard by anyone entering the premises, for whatever purpose, and should be reiterated to the film crew.

Import and export

61. The import and export of bodies or material of human origin, whether fresh, frozen, plastinated, dried or embalmed, 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 use for a scheduled purpose.

62. In the HT Act, ‘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.

63. The guidance in this section does not apply to whole bodies or parts of bodies that are historical human remains, or human remains incorporated into artefacts, which are more than 100 years old.

Imported material

64. Given the importance of consent and its role in maintaining public confidence in the use of human bodies and body parts, the HTA considers that the same

consent expectations should apply for imported bodies and body parts (as set out in paragraphs 37 to 40 in this Code) as for such material sourced domestically (within England, Wales and Northern Ireland), unless the HTA is satisfied that there are exceptional circumstances for not doing so.

65. Anyone removing, storing or using bodies or body parts imported for the purpose of public display where the import is on or after the date this Code of Practice (Version 2) comes into force should ensure that they have been sourced legally in the country of origin and the person whose body or body parts are intended for public display has given consent for this purpose. Establishments should be confident in the validity and authenticity of the documentation they intend to rely on for assurance. Furthermore, when considering the import of material, establishments should give due regard to the guiding principles referred to earlier in this Code.

66. Good practice requires that effective and reliable processes should be in place for acquiring evidence of informed consent. This means that the importer should have implemented policies and/or Standard Operating Procedures (SOPs), which clearly set out how to obtain this evidence. This includes 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.

67. Any individual or organisation wishing to import human bodies and material of human origin should be able to demonstrate that the purposes for which they wish to import such material cannot adequately be met by comparable material available from sources within England, Wales or Northern Ireland, or that it is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent.

68. 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.

69. 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.

Exported material

70. When seeking consent, donors should be advised that their samples may be exported and used abroad. SLAs should be in place to ensure that human bodies and material of human origin 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 and transported in a manner consistent with safety considerations, and with due regard to the dignity and respect that should be accorded to human bodies.

Disposal

71. Disposal of relevant material is one of the activities within the statutory remit of the HTA. Most establishments engaged in the public display of human material, particularly those that are accredited by Arts Council England under the Museums Accreditation Scheme, will have acquisition and disposal/deaccession policies that consider cultural issues, such as repatriation. Where this is not the case, the guidance on disposal in this code should be followed if material is to be disposed of.

72. The HT Act does not mandate any particular method of disposal, for example according to the type or size of the relevant material, and does not stipulate methods of disposal for specific body parts. Instead, the HTA encourages staff at HTA-licensed establishments to make decisions about the most suitable method of disposal in each case.

73. In cases where cremation is not possible, it is permissible to dispose of material or body parts which have been displayed by incineration, provided they are disposed of separately from other clinical waste. HTA-licensed establishments should have SOPs supporting the process for preparing, documenting and transporting specimens and body parts for incineration.

74. When seeking consent for use of their body or tissue for public display, individuals should be informed how it is planned that tissue will be disposed of after use and any options available.

75. Staff should be familiar with the establishment’s arrangements for disposal. This includes what is available locally, basic legal requirements and the options available to those wanting to make their own arrangements to dispose of tissue.

HTA licensing Standards

76. In order to obtain a HTA licence, the applicant must demonstrate that they and the relevant premises are suitable. The HTA will assess whether they can meet a number of core Standards, which were developed in consultation with representatives from the regulated sectors. These relate to the consent provisions of the HT Act and the regulatory requirements for governance and quality systems, traceability and premises. They reinforce the HT Act's intention that:

    a. consent is paramount in relation to activities involving the removal, storage and use of human tissue;
    b. bodies of the deceased and organs and tissue removed from bodies are treated with respect; and
    c. the dignity of the person, whether living or deceased, is maintained.

77. The HTA works with establishments through its inspection process to help them comply with these Standards.

78. Each licensed establishment is required to appoint a Designated Individual (DI) for their licence, who has a statutory responsibility under the HT Act to supervise activities taking place under a licence. The DI has a duty to ensure that suitable practices are carried out by those working under the licence, that the premises are suitable and that the conditions of the licence are complied with. By ensuring that the establishment is meeting the HTA's licensing Standards, the DI will be meeting their statutory responsibility.

79. When HTA staff undertake inspections of HTA-licensed establishments, they make judgements about the suitability of the Licence Holder (LH), the DI, the practices taking place and the premises on which they take place. They do this by assessing the establishment's compliance with the HTA's licensing Standards, which reflect the guiding principles set out in Code A and provide the operational detail of how establishments should meet the requirements of the HT Act and the Codes of Practice.

80. The HTA's licensing Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the Standards flow.

Consent (C)

81. Establishment's meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The Standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

82. Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

Traceability (T)

83. Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and the HTA expects establishments to take a proactive approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

Premises, facilities and equipment (PFE)

84. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place and that they are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

85. The HTA licensing Standards which are applicable to the Public Display sector are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

Annex A

Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.

2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes[1] in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:

   a. the person died before the HT Act came into force on 1 September 2006; and,
   b. at least 100 years have elapsed since the date of the person's death.

4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.

5. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

6. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUTCD. Establishments licensed under the Q&S Regulations should refer to the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

7. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets quality and safety standards for organ donation and transplantation. The requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations

[1] Defined by the HT Act and explained in further detail in the glossary.

2012 (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA's The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

8. On 1 December 2015 a deemed consent system for organ donation after death became operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA's regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent for deceased organ donation system.

Scotland

9. The HTA's remit does not extend to Scotland, and therefore the HTA's Codes of Practice do not apply to establishments in Scotland.

10. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA's remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland, which the Scottish Health Department letter issued on 20 July 2006[2].

11. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this Code does not apply in Scotland.

Status and use of the Codes of Practice

12. Throughout the Codes, the word '**must**' applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA's licensing Standards. We use the word '**should**' when providing advice on how to meet these requirements.

[2] Ref: NHS HDL (2006) 46. (updated 2017)

13. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

Other advice and guidance

14. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA's website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others' guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.

15. The HTA's Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Annex B

Scheduled purposes and licensing in the Public Display sector

1. To understand fully the requirements of the HT Act, knowledge of scheduled purposes and licensable activities is required.

2. The HT Act differentiates between scheduled purposes, for which consent is required, and activities for scheduled purposes, which are licensable. This is an important distinction, and one which sometimes causes confusion because in not all cases are both consent and a licence required.

Scheduled purposes

3. There are three scheduled purposes which relate to the public display sector; consent is required to store or use bodies or relevant material for all of them:

    a. public display, which applies to material from the living and deceased;
    b. research in connection with disorders or the functioning of the human body, which applies to material from the living and the deceased;
    c. education or training relating to human health, which applies to material from the deceased only.

4. Note that only (a) requires consent from the person themselves; where the person has since died, their consent must be in writing and have been witnessed and attested. Where the person has died, consent for the scheduled purposes in (b) and (c) can be provided by the deceased person's nominated representative or relatives (those in a qualifying relationship to the deceased before they died; see Code A for more information).

Licensable activities

5. There are two licensable activities which are relevant to the public display sector:

    a. the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes; and

    b. the use of the body of a deceased person or relevant material which has come from the body of a deceased person for the purpose of public display.

6. The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, exempt from licensing the storage of relevant material from a human body for use for public display, where the material is from a living person. That means that a licence is

not required for the storage or public display of body parts or tissue from the living.

Annex C Licensing and consent flowcharts

Licensing and consent requirements for public display of human tissue from the living

Storage of and/or use of human tissue from the living

1. Consent required? **YES**
    - Unless obtained before 1 September 2006

2. Licence required? **NO**

Licensing and consent requirements for public display of human tissue from the deceased

Storage of and/or use of human tissue from the deceased

1. Consent required? **YES**
    - Unless obtained before 1 September 2006; or
    - The person died before 1 September 2006 and 100 years have elapsed since their death

2. Licence required? **YES**
    - Unless the person died before 1 September 2006 and 100 years have elapsed since their death

Annex D

HTA licensing Standards: Public Display sector

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice

a. If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained.

b. If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance.

c. Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

C2 Information about the consent process and the activity for which consent is sought is provided

a. There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice

b. Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a. There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

i. an overarching policy on the care and treatment of exhibits containing human tissue;

ii. seeking consent for donation of bodies and human tissue for public display;

iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally; iv. specimen preservation, monitoring and conservation;

v. control of environmental conditions;
vi. the management of sensitive material, such as fetal remains;
vii. transportation of specimens e.g. on loan to or return to other collections;
viii. the disposal/deaccession of specimens;
ix. storage contingency arrangements;
x. the creation, amendment, retention and destruction of records;
xi. the management of incidents and complaints.

b. There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c. Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

d. Policies and procedures are reviewed regularly and are version controlled.

GQ2 There is a documented system of audit

a. There is a documented system of audit, which includes records of traceability and specimens.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a. There are clear reporting lines and accountability, and documented roles and responsibilities.

b. There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

GQ4 There is a systematic and planned approach to the management of records

a. There are suitable systems for the creation, review, amendment, retention and destruction of records.

b. Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that untoward incidents are investigated promptly

a. There is a system for reporting and investigating serious untoward incidents.

b. Corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored

a. Risk assessments are documented.

b. Risk assessments set out steps taken to mitigate risks

c. Risk assessments are reviewed regularly

d. Staff can access risk assessments and are made aware of them in training

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue

a. Bodies and human tissue are traceable through a unique identification number or code.

b. The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

T2 Records of traceability are maintained

a. Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.

b. Disposal or de-accession records include the date, reason and method of disposal/deaccession.
c. Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment

PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue

a. Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

b. The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c. Staff have access to the protective clothing, materials and equipment they need.

d. A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

e. There are policies in place to review and maintain the safety of staff and visitors.

f. The premises are secure with controlled access to bodies, human tissue and records.

g. Security measures include the use of lockable display areas and alarm systems

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a. Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

b. Critical storage conditions are monitored and recorded.
c. There are systems to deal with emergencies.

d. There is a documented contingency plan for storage of bodies and human tissue.

Glossary / definitions

Anatomical examination: Macroscopic examination by dissection for the purposes of teaching or studying, or researching into, the gross structure of the human body.

Anatomical specimen: The body of a deceased person, including separated parts of such a body, to be used for the purpose of anatomical examination.

Appropriate consent: Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.

Bone marrow: A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.

Cells: Individual human cells or a collection of human cells that are not bound by any form of connective tissue.

Clinical waste: The Controlled Waste Regulations 1992 define clinical waste as any waste which consists wholly or partly of: human or animal tissue; blood or other body fluids; excretions; drugs or other pharmaceutical products; swabs or dressings; or syringes, needles or other sharp instruments which, unless rendered safe, may prove hazardous to any person coming into contact with it.

Clinical waste also refers to any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, teaching or research, being waste which may cause infection to any person coming into contact with it.

Coroner: Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.

Designated Individual (DI): The person named on a licence issued by the HTA, under whose supervision licensed activities are carried out. The DI has a statutory responsibility to ensure that those carrying out licensed activities, and their practices, are suitable, and that the conditions of the licence are met.

DNA: DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics.

Find out more information about the HTA's role with regards to DNA on the HTA's website.

Donation: The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.

Donor: Every human source, whether living or deceased, of tissue, cells, organs or part organs.

Embalming: The use of chemicals to preserve human tissue.

Existing holding: Material from the living or deceased that was already held for use for scheduled purposes when the Human Tissue Act came into force on 1 September 2006.

Export: The movement of human tissue from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.

Human application: In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.

Import: The movement of human tissue into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland.

Incineration: A process used to destroy human body parts. Incineration of human tissue as clinical waste is normal practice and is subject to separate regulation. Incineration does not usually have any associated ceremony. Technically, cremation and incineration are similar processes, both using burning to reduce part or whole deceased human bodies to basic chemical compounds in the form of ashes.

Licensed premises: Where the licensed activity takes place.

Licensing: A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified standards set by the HTA.

Nominated representative: A person appointed by a person to represent them after their death for the purposes of activities under the Human Tissue Act for which consent is required. A nominated representative may be entitled to consent to the

removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.

Organ: Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.

Pathology: The science of the causes and effects of diseases.

Peripheral blood stem cells (PBSCs): Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the blood stream by giving a drug, and collected with an apheresis machine.

Plastination: A method of preserving human tissue using plastics.

Post-mortem examination: Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.

Practitioner: A person working with relevant material in an establishment licensed by the HTA.

Procurement: The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.

Relatives: Throughout the Codes, the term ‘relatives’ should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the Human Tissue Act.

Relevant material: 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. See policy guidance on how to apply this definition on the HTA’s website.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.

Scheduled purpose: Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the Human Tissue Act also refer to the scheduled purposes. Scheduled purposes are divided into those which apply general, and those which apply to the deceased only.

- 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.

Service Level Agreement (SLA): A formal agreement that sets out the roles and responsibilities of two parties. An SLA cannot be used to provide a third party that is not licensed by the HTA with the authority to undertake licensable activities on behalf of a licensed establishment, only a Third Party Agreement (TPA) may be used for that purpose. Neither is it sufficient for governing the supply of goods or services which may affect the quality or safety of tissues and cells.

If two establishments are licensed by the HTA and one undertakes licensable activities on behalf of the other, an SLA setting out roles and responsibilities is sufficient to document the working relationship between the two licensed establishments.

Standard Operating Procedure (SOP): A document that sets out the established process to be followed to complete a task.

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

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

Valid consent: Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.