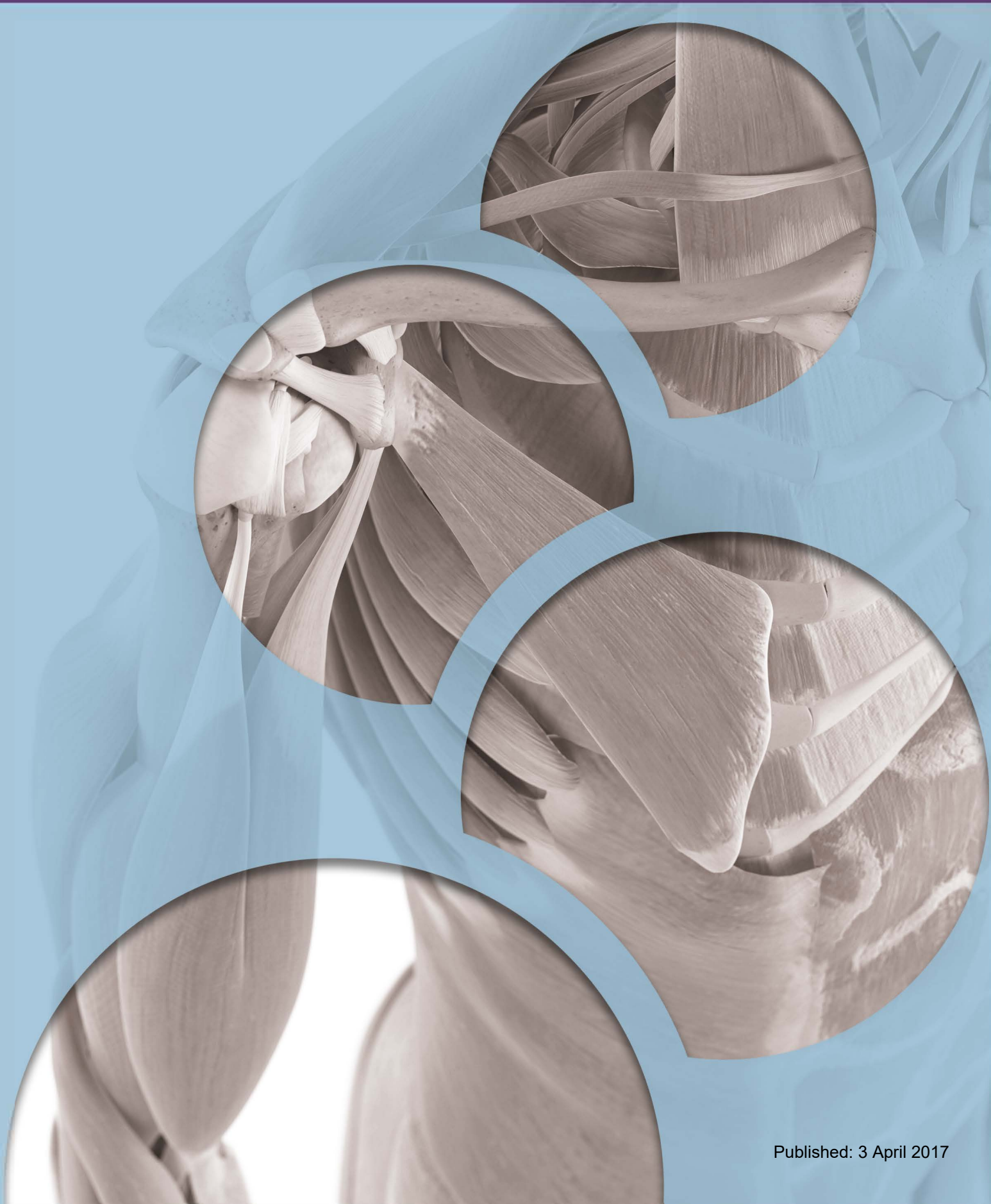


Code of Practice and Standards



Code C: Anatomical examination

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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. With regard to the anatomy sector, these principles translate into actions which ensure that potential donors are given the information they need to make the best decisions requiring their consent. It is also incumbent on regulated organisations to manage human material in accordance with expressed wishes, removing, storing, using and disposing material properly and respectfully.
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 Anatomy Code

9. Human bodies and body parts are used to teach students and to train surgeons and other healthcare professionals. The HTA licenses and inspects organisations, such as medical schools, that carry out these activities in England, Wales and Northern Ireland. We do this to provide assurances to the public that bodies or tissue from the deceased are given with proper consent, and are managed appropriately. We also provide advice and guidance to potential donors, the public and people whose work is covered by our regulatory framework.

Scope of this Code

10. This Code is primarily intended to guide those people whose work we regulate, primarily through licensing and inspections, but it may be useful to members of the public, particularly potential donors and their relatives.
11. In addition to providing information on statutory and regulatory requirements, it also makes reference to the HTA licensing Standards that HTA-licensed organisations are expected to meet.
12. This Code should be read in conjunction with Code A, *Guiding principles and the fundamental principle of consent*, which sets out the principles which govern the conduct of activities within the HTA's remit and informs the content of this and the other Codes.

Offences under the HT Act

13. 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 Anatomy sector, the offences are as set out below.
14. 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 do 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.

15. Section 16(1) and (2) of the HT Act prohibit the following activities, except under the authority of a licence:
 - a) the carrying out of an anatomical examination;
 - b) the removal of relevant material from the body of a deceased person for use for scheduled purposes other than transplantation;
 - c) the storage of an anatomical specimen; and
 - d) the storage of the body of a deceased person, or relevant material which has come from a human body, for use for scheduled purposes.
16. 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.
17. Sections 30 and 31 of the HT Act contain special provisions for anatomical specimens (and former anatomical specimens) to be lawfully held on unlicensed premises in certain circumstances and these are covered later in this Code.

Structure and navigation

18. As there are specific consent requirements for anatomical examination, the first part of this Code focuses on these.
19. The Code then sets out the relevant requirements and expectations for establishments licensed in the Anatomy sector, supported by good practice examples.
20. At the end of this Code, there is a section on the HTA licensing Standards.
21. 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.

Providing information to potential donors

22. It is important that a person wishing to donate their body for anatomical examination is given all the information necessary to make an informed decision. This information should be made available in a variety of formats (electronic, written and oral) so that donors may choose which is most appropriate for them. Information is also provided for potential donors on the HTA's website.
23. The HTA has produced a model bequeathal booklet and a model body donation consent form to aid anatomy establishments.

Obtaining appropriate consent

24. Under the HT Act, appropriate consent for anatomical examination can only be given by individuals who choose to donate their body; consent cannot be given by someone else.
25. Documented and valid consent for anatomical examination given before 1 September 2006 is treated as appropriate consent under the HT Act.
26. For consent for body donation to be valid under the HT Act, it must be in writing and:
 - a) signed by the donor in the presence of at least one witness who attests their signature; or
 - b) signed by a person at the direction of the donor, in their presence and in the presence of at least one witness who attests that person's signature. The HTA accepts that it may not always be possible to obtain written consent from the individual who has chosen to donate their body or part of their body for anatomical examination, for example when a person with sufficient mental capacity is physically unable to write. The HTA has therefore produced a model form for a person to sign on behalf of a donor. In these circumstances, the HTA advises that:
 - i. the potential donor has sufficient mental capacity to make the decision to donate their body for anatomical examination and is able to indicate their wish verbally or physically;
 - ii. the person should sign their own name, state that they have signed at the direction of the donor and explain the circumstances of this direction;

- iii. the form should then be signed by the witness before being submitted to the receiving institution.

This procedure must occur prior to the donor's death. The consent form cannot be signed by the third party after death has occurred.

Example of good practice

A widower had a stroke that left him unable to communicate in any form, including in writing. Many years ago, when he was well, he expressed an interest in donating his body for medical teaching after his death but did not take the matter further. Now the man is dying and his daughter wants her father's wishes to be complied with. Given the lack of documented consent and the inability to assess mental capacity, there is no way to confirm that the man wishes to donate his body for anatomical examination. Therefore, the offer of donation must be declined by the anatomy facility.

27. Anyone wishing to donate their body, or part of their body, for anatomical examination should preferably use a consent form from the facility of their choice, which should be kept as part of the donation records. The HTA has produced a model body donation consent form, which can be modified and adopted by HTA-licensed establishments.
28. Individuals may also indicate their choice to donate their bodies for anatomical examination in their will. In this case, an individual should be encouraged to complete and return a consent form from the facility of their choice and to insert a copy in their will. The potential body donor should be made aware that, although a consent form does not have to be used in their will, to avoid confusion the wording of their consent should resemble the wording on the consent form provided by the establishment to which they wish to donate their body.
29. Medical school staff are sometimes faced with the challenge of deciding whether the consent given by potential donors, sometimes many years before their death, is valid if it contains wording inconsistent with terms used in the HT Act.
30. 'Anatomical examination' is not a term commonly used by the general public, and therefore it may not be used in written consent expressed in personal letters or wills. This means that medical schools can be put in a difficult position of deciding whether consent is valid or not when they receive written consent

documents which use different terminology, such as 'use for medical research' or 'medical science'. Use of human tissue in research or training are purposes listed separately to 'anatomical examination' in the HT Act and therefore consent using these terms may raise issues about whether the donor intended their body to be used only in research projects or in training, rather than to teach anatomy through dissection. A donation may be declined in cases where the terminology used in the written consent is not clear.

31. When written consent includes terminology other than 'anatomical examination', and relatives or nominated representatives can confirm and will put in writing that use for the scheduled purpose of anatomical examination was what the donor had intended, then it is reasonable to accept the body for that purpose. Establishments should not accept donations for anatomical examination where there are factors in the form of the written consent itself which would appear to rule out teaching, studying or researching into the structure of the human body. Where there are no relatives or nominated representatives, or they were unaware of the donor's wishes, or hold conflicting opinions and therefore cannot provide reliable clarification of the donor's intent, the consent remains ambiguous and establishments are advised to decline the donation.
32. It is essential that, where establishment staff have had to take a pragmatic and evidence-based decision, adequate records to demonstrate the rationale behind the decision are kept.
33. Where the validity of the consent to anatomical examination is questionable and this guidance does not provide all the necessary clarification, further information and advice can be obtained from the HTA.
34. Under the HT Act, appropriate consent is not needed for removal, storage and use of material from a deceased body for anatomical examination, if at least 100 years have elapsed since the date of the person's death. Appropriate consent is also not needed if the body has been imported; however the HT Act makes consent the fundamental principle underpinning the lawful storage and use of human tissue and so the HTA considers it good practice to ensure mechanisms are in place in the source country for obtaining consent.
35. The import and export of bodies or body parts is discussed in paragraphs 62-77 of this Code.
36. Under the HT Act, the provisions for lawful storage of a body for the purpose of anatomical examination are different from the provisions for lawful use of a

body for anatomical examination. Legislative changes to certification or registration of death may amend these provisions in the future.

37. Storing a body for anatomical examination is lawful provided that:
 - a) there is appropriate consent; and
 - b) there is a signed Medical Certificate of Cause of Death under the Births and Deaths Registration Act 1953 or, in the case of Northern Ireland, the Births and Deaths Registration (NI) Order 1976.
38. This allows establishments to proceed to storage and timely preservation of a body donated for anatomical examination, if registration of death has been delayed.
39. Using a body for anatomical examination is lawful provided that :
 - a) there is appropriate consent; and
 - b) the person's death has been registered.
40. In summary, to lawfully store a body for anatomical examination, appropriate consent must be in place and the death certificate must be signed. To lawfully use a body for anatomical examination, appropriate consent must be in place and the death must be registered. However, the HT Act makes it clear that an offence is not committed if a person stores the body where they reasonably believe that consent is in place and the death certificate has been signed. An offence is also not committed if a person uses a body where they reasonably believe that consent is in place and the death has been registered.

Care of cadaveric material

41. During anatomical examination and storage, all parts of the body should be treated with due respect and consideration.

Example of good practice

A university anatomy establishment provides teaching to hundreds of healthcare students each year, some of whom attend from other universities. The Designated Individual (DI) wants to ensure, to the best of her ability, that the dignity of deceased people is upheld. She acknowledges that physical supervision of all students at all times would be impossible but wants to put effective safeguards in place. After thorough discussions with the establishment's staff, the DI puts a number of measures in place, including:

- a) a review of the security of the premises;
- b) a registration system, utilising a signing-in book so that the DI and other persons working under the HTA licence are aware of who is in the establishment at any given time. The reason for the visit should be recorded in the signing-in book, along with the name of the person under whose supervision the visitor will be;
- c) revising the local Code of Conduct to reflect the requirements of the HT Act and the HTA Code of Practice on Anatomical examination;
- d) a declaration to be signed by all relevant visitors to confirm that they have read and understood the local Code of Conduct;
- e) prominent signs relating to important aspects of the local Code of Conduct.

The making and displaying of images

42. The making and displaying of images (including photographs, films and electronic images) falls outside the scope of the HT Act. However, the HTA requires DIs to put systems in place to ensure suitable practices are carried out.
43. The HTA endorses the guidance on images provided by the General Medical Council (GMC) in its publication [Making and using visual and audio recordings of patients.](#)
44. Ensuring suitable practices where licensable activities are concerned includes the DI ensuring that the dignity of deceased people is maintained at all times.

Therefore, the HTA expects DIs to put systems in place to prevent the inappropriate use of images.

Transfer or loan of cadaveric material

45. Bodies or body parts must be kept on licensed premises, unless the DI has given written permission to a suitable nominated person to move them to appropriate unlicensed premises, and to store and use them for authorised purposes.
46. Bodies or body parts may only be transferred or loaned for purposes for which consent was originally given.
47. Anatomical specimens or former anatomical specimens may be loaned by a DI, providing that they put the permission for each loan in writing. The loan should be for a defined time period and the written agreement should be signed and a copy kept by both parties.
48. Records should be kept of any loans, including relevant details of:
 - a) the specimen/s covered by the agreement;
 - b) the person authorised to hold the specimen(s);
 - c) the address where the specimen(s) will be held;
 - d) the purpose for which the specimen(s) is/are being moved;
 - e) the purpose for which the authorised person may have possession of the specimen(s);
 - f) the period for which the loan is so authorised.
49. The HTA has produced a model authorisation form for loan of anatomical specimens.
50. The DI remains responsible for the material for the duration of the loan. The HTA recommends that the borrower be required to agree to comply with the HT Act and this Code of Practice, and to provide appropriate storage.

Example of good practice

A lecturer in a university physiotherapy department wishes to teach his undergraduate students on the anatomy of the vertebral column. Rather than using plastic teaching models, he wishes to teach a small tutorial group using a prosected specimen. The teaching session will be one component of a special study day for healthcare students being held at a different university campus, which does not hold a relevant HTA licence. The lecturer arranges a meeting with the DI of the anatomy establishment to discuss whether an appropriate specimen could be loaned for this purpose. The DI is keen to help and is aware that the HT Act allows for the possession of anatomical specimens and former anatomical specimens away from licensed premises. Both parties refer to this Code and a written loan agreement is created from the HTA's model loan form. The loan agreement is signed by both parties and each party keeps a copy as a record of the loan.

51. Loan arrangements do not remove the need for satellite sites in the anatomy sector.
52. A suitable loan would typically involve a specimen or small numbers of specimens being transferred from an HTA-licensed anatomy establishment to a suitable place for a short period of time, such as for a teaching session.
53. A suitable satellite site would typically be a specialist facility, which the main establishment (the hub) supplies with cadaveric material on a regular basis, or for an extended period of time, for a programme of research or education/training relating to human health.
54. Satellite site applications will be assessed by the HTA to determine if the proposal is appropriate. As with all HTA satellite sites, anatomy satellite sites must meet the following requirements:
 - a) they must undertake a lower level of licensable activities compared with the main establishment;
 - b) they must have the same governance framework as the main establishment and have at least one Person Designated;
 - c) they must be inspected regularly by the DI, at least twice per year.

Documentation and record keeping

55. All places where anatomical examination is carried out should keep records in a permanent form for each body or body part in its possession (or in the possession of any other person authorised by the DI to hold the anatomical specimen). These records should be held on the premises where the donated body was first received, and on any other premises to which the body or body parts have been moved.
56. Records to support traceability are essential, particularly where material is difficult to label.

Example of good practice

Where plastination of specimens takes place, labelling may not be practically possible during the plastination process and so the co-plastination of parts that are indistinguishable from each other must be avoided, such as two normal hearts. A detailed record of each of the parts must be kept in a manner which allows full traceability of each part at every stage.

Example of good practice

If it is difficult to label small bones, establishments need to consider how they can ensure traceability, such as by colour-coding catalogued collections.

57. It has been concluded that records relating to body parts retained after anatomical examinations should be held on the premises in which the examination of the original anatomical specimen took place, and on any other premises to which the parts have been moved.
58. All records must be available for inspection and review.

Charging

59. Charges may be applied to cover the costs of transporting and embalming bodies and of preparing specimens for use at other establishments. These charges should fairly reflect the costs involved.
60. Donors should be told if their samples will or could be used for research involving the commercial sector. They should be given appropriate information

on the range of activities and researchers which may be involved, and whether these include commercial establishments.

61. Medical schools may charge for providing human tissue samples to other medical schools and researchers, including those working for private companies, so that their running costs are recovered. Where cost recovery, or any other charging mechanism, is in place it is important that establishments are able to satisfy themselves that the information provided to potential donors is sufficient to ensure they understand that their tissue may be shared, subject to a fee being charged. The HTA also recommends that establishments ensure transparency by providing easily accessible information about how and why they charge, and to whom they will supply tissue samples. This is important to ensure that the consent sought from donors is fully informed.

Import and export of bodies or body parts

Import

62. Bodies and body parts are imported into England, Wales and Northern Ireland for use in education or training relating to human health or for anatomical examination. The import and export of relevant material is not licensable under the HT Act. However, the storage and use of bodies or body parts for education or training relating to human health or for anatomical examination is licensable.
63. The geographical scope of “import” and “export” according to the HT Act is as follows:
 - a) “import” means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;
 - b) “export” means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.
64. Imported material should be obtained, used, handled, stored, transported and disposed of in accordance with the consent which has been obtained. Importers should satisfy themselves and be able to demonstrate to the HTA that, in the countries from which they seek to import tissue, the seeking of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained.
65. All persons or organisations wishing to import human bodies, body parts and tissue into England, Wales and Northern Ireland should be able to demonstrate that the purposes for which they wish to import such material cannot be

adequately met by comparable material available from sources within those countries, or is for a particular purpose which justifies import. Importers should assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent. They should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service, cost effectiveness, or scientific or research need. Such documentation should be available for inspection by the HTA.

66. The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts and tissue from the living or the deceased, for the purposes specified in the HT Act. 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.
67. 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.
68. The import of fresh frozen bodies and body parts for the scheduled purpose of 'education and training relating to human health' is a common practice for some HTA-licensed establishments. Fresh frozen material is primarily used for surgical training. The benefit of using this material is that it provides healthcare professionals with opportunities to practice life-like surgical techniques and procedures without posing any risks to patients.
69. There are also potential health and safety risks associated with fresh frozen cadaveric material. As the suitability of donors from abroad has not been directly assessed by the DI, importing establishments should ensure that donors who have tested positive for HIV disease, hepatitis B, hepatitis C, tuberculosis, a transmissible spongiform encephalopathy (such as Creutzfeldt-Jakob Disease) and meningitis have been excluded from donation by the supplier in the source country. Donor testing should have been carried out by an accredited or licensed laboratory and all the donor information should have been reviewed and signed off before any specimen is considered available for release.
70. The HTA would expect a donor sheet to accompany any imported cadaveric material, confirming the low-risk status of the donor and including testing results.
71. The HTA expects DIs to assure themselves that all imported specimens are procured, wrapped and shipped appropriately to prevent accidental exposure

and conform to the international standards for the transport of hazardous clinical material. Detailed requirements for the carriage of '[Dangerous Goods](#)' are set out in the Technical Instructions approved and published by the International Civil Aviation Organisation (ICAO).

72. As fresh frozen cadaveric material will not have been subject to any chemical preservation, such as embalming, the HTA also expects establishments to adhere to two guidance documents published by the Health and Safety Executive (HSE):
- a) the first document, 'Controlling the risks of infection at work from human remains', concerns the handling of cadaveric material. Although it was published primarily for those in the funeral profession, it provides useful guidance on precautionary measures to be taken by anyone who has contact with human remains, and in particular deals with the risk of infection, including the sources, transmission and host of infection;
 - b) the second piece of HSE guidance is entitled 'Safe working and the prevention of infection in the mortuary and post mortem room'. Although it was published primarily for those working in a post-mortem examination room, it provides useful guidance on the handling, storage and examination of bodies and pathological specimens, including safe working practices, health surveillance and risk assessment.
73. If any specific requests were made by the deceased regarding disposal when consent was obtained, such requests must be carried out. This may include, for example, the return of material to the country of origin.

Export

74. Material to be exported should be obtained, used, handled, stored, transported and disposed of, in accordance with the consent which has been given, with due regard for safety considerations and with the dignity and respect accorded to human bodies, body parts and tissue provided for in the Codes in England, Wales and Northern Ireland. This includes providing donors with adequate information when obtaining consent, to the effect that their material may be exported for use abroad.
75. Documented agreements should be in place to ensure that human bodies, body parts and tissue to be exported from England, Wales and Northern Ireland are used in accordance with the consent which has been obtained. Material should be handled, stored, transported and disposed of, in a manner consistent with safety considerations, and with the dignity and respect accorded to human

bodies, body parts and tissue provided for in legislation and Codes in England, Wales and Northern Ireland.

76. Although the HT Act does not provide any prohibition or restriction on the import or export of human material, imports and exports must normally be declared to HM Revenue and Customs.

Disposal

77. Processes should be in place to inform individuals, or their relatives¹, how bodies and tissue will normally be disposed of after use. Establishments should ensure that their employees are given the necessary training and support to help them identify and meet the expected range of needs and wishes of donors and their relatives.
78. Attitudes towards disposal may vary widely among cultures and religions. Staff should be sensitive to this, being aware that choices are for the individual or relative to make. Donors may wish to discuss the final disposition of their remains with relatives or others before making their choice.
79. Staff should be familiar with the establishment's arrangements, including what is available locally, and the options available to those wanting to make their own arrangements to dispose of tissue. Where appropriate, such information should be available in writing for people to take away with them. Staff should also be prepared to discuss who will be responsible for any associated costs.
80. All establishments should give particular consideration to the needs of individuals and families whose first language is not English. Any difficulties in communicating with the person concerned (for example because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (such as through an independent translator), should be recorded.
81. Disposal of relevant material is one of the statutory activities within the remit of the HTA; however, the HT Act does not mandate any particular method of disposal according to the type or size of the relevant material.

¹ 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.

82. The HTA does not stipulate methods of disposal for specific body parts and encourages staff at HTA-licensed establishments to make decisions about the most suitable method of disposal in each case.
83. In cases where cremation is not possible, it is permissible to dispose of anatomical specimens, former anatomical specimens and body parts, whether imported or not, by incineration, providing they are disposed of separately from other clinical waste.
84. It is good practice for staff at HTA-licensed establishments to agree the acceptance criteria for relevant material with their local incineration facility as part of any disposal agreements.
85. It may be that staff at HTA-licensed establishments are required to further prepare relevant material prior to it being sent for disposal by incineration. The HTA expects staff at HTA-licensed establishments to develop relevant Standard Operating Procedures (SOPs) supporting the process for preparing, documenting and transporting specimens and body parts for incineration.
86. It is good practice to retain tissue removed from the cadaver during dissection for disposal along with the body. Body parts retained after the disposal of the body, and any tissue removed from them, may be disposed of as clinical waste.
87. Thiel embalming involves the prolonged immersion of several bodies, on separate trays, in a specially designed tank. As a by-product of this embalming method, the superficial skin layer and the nails from the donors can become detached and should be disposed of as clinical waste.

HTA licensing Standards

88. 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
 - c) the dignity of the person, whether living or deceased, is maintained.
89. The HTA works with establishments through its inspection process to help them comply with these Standards.
90. 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 other persons to whom the licence applies are suitable persons 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.
91. 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.
92. 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)

93. Establishments 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)

94. 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)

95. 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 we expect establishments to take a pro-active 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)

96. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for their licensed activities and 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.
97. The HTA licensing Standards which will be applicable to the Anatomy sector from April 2017 are included at Annex B 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 purposes² 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:
 - d) the person died before the HT Act came into force on 1 September 2006; and
 - e) 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

² Defined by the HT Act and explained in further detail in the glossary.

requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 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 2006³.
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. Guidance for practitioners in Scotland is available [here](#).

³ Ref: NHS HDL (2006) 46. (updated 2017)

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.
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 and may take appropriate regulatory action in doing so.

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 this 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. Professional guidelines have been drawn up by the Anatomy Associations Advisory Committee (AAAC), formerly the Professional Guidelines and Practices (Anatomy) Committee, and are available on the websites of three professional bodies which comprise the committee, namely: Anatomical Society (AS), British Association of Clinical Anatomists and Institute of Anatomical Sciences (IAS).
16. 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

HTA licensing Standards: Anatomy sector

Consent Standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice
<ul style="list-style-type: none">a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.e) Language translations are available when appropriate.f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
<ul style="list-style-type: none">a) There is suitable training and support of staff involved in seeking consent.b) Records demonstrate up-to-date staff training.c) Competency is assessed and maintained.

Governance and quality system Standards

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

- a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.
- b) There is a document control system.
- c) There are change control mechanisms for the implementation of new operational procedures.
- d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff.
- e) There is a system for managing complaints.

GQ2 There is a documented system of audit

- a) There is a documented schedule of audits covering licensable activities.
- b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- a) Qualifications of staff and all training are recorded, records showing attendance at training.
- b) There are documented induction training programmes for new staff.
- c) Training provisions include those for visiting staff.
- d) Staff have appraisals and personal development plans.

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) There are provisions for back-up / recovery in the event of loss of records.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all adverse events are investigated promptly

- a) Staff are instructed in how to use incident reporting systems.
- b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

- a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
- b) Risk assessments are reviewed regularly.
- c) Staff can access risk assessments and are made aware of risks during training.

Traceability

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

- a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
- b) A register of donated material, and the associated products where relevant, is maintained.
- c) An audit trail is maintained, which includes details of when and where the bodies or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.
- d) A system is in place to ensure that traceability of relevant material is maintained during transport.
- e) Records of transportation and delivery are kept.
- f) Records of any agreements with courier or transport companies are kept
- g) Records of any agreements with recipients of relevant material are kept

T2 Bodies and human tissue are disposed of in an appropriate manner

- a) Disposal is carried out in accordance with the HTA's Codes of Practice
- b) The date, reason for disposal and the method used are documented

Premises, facilities and equipment Standards

PFE1 The premises are secure and fit for purpose

- a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose
- b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained

- c) There are documented cleaning and decontamination procedures

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

- a) There is sufficient storage capacity
- b) Storage arrangements ensure the dignity of the deceased
- c) Storage conditions are monitored, recorded and acted on when required
- d) There are documented contingency plans in place in case of failure in storage area

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

- a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept
- b) Users have access to instructions for equipment and are aware of how to report an equipment problem
- c) Staff are provided with suitable personal protective equipment

Glossary

Term	HTA definition
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.
Cadaver	The body of a deceased person.
Cells	Individual human cells or a collection of human cells that are not bound by any form of connective tissue.
Clinical waste	<p>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.</p> <p>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.</p>

Term	HTA definition
Cremation	The use of burning to reduce part or whole deceased human bodies to basic chemical compounds in the form of ashes. Cremation is used as an alternative to burial and is often associated with a religious and/or spiritual ritual. Cremation takes place within a registered crematorium under the oversight of a Registrar, and the relatives of the deceased may be present. Cremation is regulated in England and Wales by a permit issued by Local Authority Regulators and in Scotland by SEPA, as required by the Secretary of State's Guidance for Crematoria PG5/2(12).
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	<p>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.</p> <p>Find out more information about the HTA's role with regards to DNA on the HTA's website.</p>
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.
Export	The movement of human tissue from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland.
Former anatomical specimen	An organ or body part donated for anatomical examination which is retained once the examination of the rest of the body has been completed.
Hub	Where the same licensed activities are carried out at different locations under the same governance arrangements, one can act as the hub premises and the other(s) can be a satellite site. The hub and satellite sites must share the same Designated Individual (DI).

Term	HTA definition
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 2004 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.

Term	HTA definition
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.
Person Designated (PD)	A person working under an HTA licence acting under the direction of the Designated Individual.
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 HT Act.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue 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.

Term	HTA definition
Satellite site	Where the same licensed activities are carried out at different locations under the same governance arrangements, one can act as the hub premises and the other(s) can be a satellite site. The hub and satellite sites must share the same Designated Individual (DI).
Scheduled purpose	<p>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 HT Act also refer to the scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</p> <ul style="list-style-type: none"> • 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.
Standard Operating Procedure (SOP)	A document that sets out the established process to be followed to complete a task.
Thiel embalming	A type of whole-body embalming used in the anatomy sector.
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.