

Code of practice for consultation

Public display

Code 7

This code of practice is for consultation purposes only and has not received Parliamentary approval. You should continue to use the current versions of the codes (available at: www.hta.gov.uk/guidance/codes_of_practice.cfm) until this revised code has been approved.

Contents

	Paragraphs
Introduction	1–24
<ul style="list-style-type: none">• About the Human Tissue Authority• Legislation and statutory framework• Codes of practice	1 –6 7–14 15–24
Scope of this code	25–35
<ul style="list-style-type: none">• Definition of public display• Exemption from public display• Photographic/electronic images	30–32 33 34–35
Structure and navigation	36–38
Status of this code	39
Consent	40–49
<ul style="list-style-type: none">• Obtaining consent	45–49
Licensing	50–66
<ul style="list-style-type: none">• Material over 100 years old• Loans to other museums• ‘Under 20 items’ rule• Licensing and photographic / electronic images• Licensing standards	58–59 60–61 62 63 64–66

HTA standards for public display	67–95
• Governance and quality systems	68–80
• Premises, facilities and equipment	81–95

Appendices

Appendix A: Scheduled purposes and licensable activities

Appendix B: Licensing and consent flowcharts

References

Glossary

Introduction

About the Human Tissue Authority

Role of the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_6#sch1] established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue (referred to as relevant material in the HT Act). Activities covered by the HT Act are referred to as scheduled purposes.
2. The HTA has several statutory functions. One is to inform the public, professionals and the Secretary of State for Health about issues within our remit. We meet this requirement for professionals by providing guidance, including codes of practice, to support good practice.

Regulation through licensing

3. Another statutory function is to regulate, through licensing, a number of sectors and to carry out inspections to ensure licence conditions are being met. The HTA publishes standards that licensed establishments must meet: on consent; governance and quality systems; premises; facilities and equipment; and disposal. The sectors licensed under the HT Act are:
 - Anatomy
 - Post-mortem services
 - Human application (transplantation of tissues and cells; see below)
 - Research
 - Public display
4. The HTA is the Competent Authority in the UK responsible for ensuring the safety of human tissues and cells that are used for transplantation in compliance with the European Union Tissues and Cells Directives (EUTCD).

Regulation of living and deceased donation

5. A third statutory function is the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. The HTA, Independent Assessors and Accredited Assessors who work on behalf of the HTA, assess whether consent requirements for donation have been met, and act as

representatives for the donors. The HTA also regulates living donation on behalf of the Scottish Government.

6. The HTA also oversees the consent requirements of the HT Act for deceased organ donation.

Legislation and statutory framework

Human Tissue Act 2004 [www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1]

7. Consent is the fundamental principle of the HT Act. The legislation covers England, Wales and Northern Ireland, and sets out the legal framework for:
 - the storage and use of human tissue from living people.
 - the removal, storage, and use of tissue from the deceased.
8. Regulations made under the HT Act, which provide more detail, include:
 - The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplant) Regulations 2006 [www.opsi.gov.uk/si/si2006/draft/20064576.htm]
 - The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 [www.opsi.gov.uk/si/si2006/20061260.htm]
9. Consent for diagnosis or treatment is not in the scope of the HT Act.

Human Tissue (Scotland) Act 2006

[www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1]

10. The HT Act 2004 covers England, Wales and Northern Ireland, and there is separate legislation for Scotland, the Human Tissue (Scotland) Act 2006.
11. The HT (Scotland) Act is based on authorisation, rather than consent, but both are expressions of the same principle.
12. Guidance on the Human Tissue (Scotland) Act 2006 is available in the Scottish Health Department Letter: HT (Scotland) Act 2006: A Guide to its Implications for NHS Scotland

[[www.hta.gov.uk/_db/_documents/Information_about_HT_\(Scotland\)_Act.pdf](http://www.hta.gov.uk/_db/_documents/Information_about_HT_(Scotland)_Act.pdf)] and practitioners working in Scotland should ensure they are familiar with this guidance.

Human Tissue (Quality and Safety for Human Application) Regulations 2007

13. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) govern the quality and safety of tissues and cells (not including solid organs) used for transplantation. The Q&S Regulations brought the EUTCD into force in the UK, including Scotland
[\[www.opsi.gov.uk/si/si2007/uksi_20071523_en_1\]](http://www.opsi.gov.uk/si/si2007/uksi_20071523_en_1)
14. There is no code of practice for establishments using tissues and cells for transplantation. However, the HTA issues Directions for these establishments which set out expected standards. Directions 001/2006 summarise the requirements of the parent and first technical Directive of the EUTCD (Directives 2004/23/EC and Directive 2006/17/EC). Directions 002/2007 set out the requirements of the Regulations 2007 and the second technical Directive (Directives 2004/86/EC), and supplement and amend Directions 001/2006. [link to Directions page of website]

Codes of practice

About the codes

15. The codes of practice give practical guidance to professionals carrying out activities which lie within the HTA's remit. They may also be of interest to members of the public. The first editions of the codes have been revised to reflect our experience of regulation. We have made the codes more relevant to the sectors we regulate by including case studies and examples; and have restructured them in a way that makes them more user-friendly.
16. They are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA website.
17. Failure to follow a code of practice is not in itself a criminal offence under the HT Act, but the HTA may take a breach into account when carrying out its regulatory responsibilities. For licensed establishments, adherence to the HTA's codes of practice is assessed as part of the licensing and inspection activities.

18. The HTA has now published nine codes of practice, which are listed below:
[www.hta.gov.uk/guidance/codes_of_practice.cfm]
1. Consent
 2. Donation of solid organs for transplantation
 3. Post-mortem examination
 4. Anatomical examination
 5. Disposal of human tissue
 6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
 7. Public display
 8. Import and export of human bodies, body parts and tissue
 9. Research
19. All nine codes of practice have been brought into force by HTA Directions and are either new or replace the codes previously published by the HTA.
[www.hta.gov.uk/guidance/licensing_guidance/expected_standards_directions.cfm]

Using the codes

20. The codes complement each other and should be read alongside other relevant guidance, either referenced in the text or provided on the HTA website.
21. The codes of practice are available in pdf form for printing, and in HTML format, which allows the reader to navigate through the codes more easily when viewed online.
22. The HTA will update these codes from time to time, and will issue Directions to bring them into force following the appropriate approval process.

Other advice and guidance

23. The HTA website provides extensive guidance to help ensure that the sectors we regulate comply with the law and embrace best practice. This includes guidance for licensed sectors and the transplant community, patient and public leaflets, and an e-newsletter.

24. A number of other organisations have also produced guidance on issues in the HTA's remit. Where this has been produced in collaboration with the HTA, it will appear on our website. But as a general rule, we would always advise that the HTA's codes of practice and other guidance are 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.

Scope of this code

25. The display of human bodies and relevant material is not new to the UK, but it has primarily been the preserve of establishments involved in medical education and training and a small number of specialist museums.
26. Although advice and guidance for the care and display of human remains has been available from the Department for Culture Media and Sport (DCMS) since 2004 (see paragraph 29 below), prior to the HT Act the activity of public display was not covered by statute so there was no restriction on the display of human bodies and relevant material.
27. Under the HT Act, public display of bodies of the deceased and relevant material from the living or the deceased is both a scheduled purpose for which consent is required and in some cases a licensable activity. The difference between scheduled purposes and licensable activities is explained in Appendix A.
28. The consent and licensing requirements of the HT Act are covered in detail in this document, and examples are included to provide practical advice. The main points are that:
- i. there must be consent from living or deceased people (given before they died) before their bodies or any relevant material can be stored or used for public display
 - ii. a licence is required for the storage for public display or the actual public display of bodies or relevant material from deceased people, except where more than 100 years have elapsed since the person's death
29. A key principle on which the HT Act is based is that all human bodies and relevant material within its scope should be treated with respect and dignity. This principle is also reflected in guidance on the curating, care and use of human remains given by the DCMS in its document *Guidance for the care of human remains in museums* [www.culture.gov.uk/NR/rdonlyres/0017476B-3B86-46F3-BAB3-11E5A5F7F0A1/0/GuidanceHumanRemains11Oct.pdf].

The DCMS guidance covers some areas of museum activity which are also affected by the HT Act. However, the DCMS guidance has a longer historical reach, dealing with material collected before the period covered by the HT Act. The legislative requirements of the HT Act and the guidance given in this code do not apply to bodies or relevant material if more than 100 years have elapsed since the date of the person's death.

Definition of public display

30. The HT Act does not contain a definition of public display but the HTA regards a public display as:

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.

31. The meaning of the term 'relevant material' is explained in the glossary.
32. Questions have arisen since the commencement of the HT Act about what constitutes an exhibition or display, and also how we define 'public'. Throughout this guidance, examples are given to help establishments determine whether or not their activities fall within the remit of the HTA.

Exemption from public display

33. There are two activities which are exempt from the legislation:
- i. Display for the purposes of enabling people to pay their final respects to the deceased or a display which is incidental to the deceased's funeral (HT Act, Part 3, Section 54 5).
 - ii. Bodies or relevant material displayed in a place of public religious worship and used for the purposes of religious worship or contemplation (HT Act, Part 2, Section 40).

Photographic / electronic images

34. The HT Act is silent on the display of photographic or electronic images whether moving (e.g. in a broadcast or transmission) or static (e.g. in a text book). However, the HTA requires Designated Individuals (DIs) to put systems in place to ensure suitable practices are carried out.
35. 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 [www.gmcuk.org/guidance/current/library/making_audiovisual.asp#1]. Further

guidance on images is provided later in this document (see paragraphs 44 and 63).

Structure and navigation

36. This code has two central sections dealing with consent and licensing. In each of these sections, the requirements of the HT Act and any exemptions are explained. In some cases, where there are specific consent and licensing requirements relating to a particular issue, headings are repeated.
37. These sections are followed by information on the HTA standards and how establishments are expected to demonstrate compliance.
38. Appendix A explains the difference between licensable activities and scheduled purposes. This distinction has sometimes caused confusion.

Status of this code

39. The HTA published interim guidance in September 2006 in the document guidance on public display. Public display falls within the HTA's statutory remit. This code on public display replaces the previous guidance document and has received Parliamentary approval. The code seeks to provide more detailed guidance to establishments publicly displaying human bodies or relevant material or storing them for the purpose of public display.

Consent

40. The fundamental principle of the HT Act is the requirement that consent is obtained for the removal, storage and use of relevant material which has come from a human body for certain purposes, including public display. Therefore, anyone removing, storing or using material, whether from a deceased person or from a living person, for the purpose of public display must be satisfied that consent is in place.
41. Consent is not, however, required for the public display of bodies or relevant material from the body of a person, if more than 100 years have elapsed since the date of the person's death.
42. Furthermore, 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, that is 1 September 2006 (HT Act Part 1, Section 9).

Example – A surgeon has amassed a private collection of preserved human body parts and tissue which she 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 that died less than 100 years ago.

43. The consent provisions of the HT Act do not apply to material that has been imported. Nonetheless, the HTA considers it good practice for establishments involved in public display to put in place effective and reliable processes, which provide assurance that human tissue which is to be imported, is obtained with valid consent. Guidance for importers wishing to import human bodies or relevant material from abroad into England, Wales and Northern Ireland, is set out in the code of practice on the Import and export of human bodies, body parts and tissue [www.hta.gov.uk/guidance/codes_of_practice.cfm]. Directions which bring into force the first edition of this code, as provided for under Section 26 of the HT Act, may be found at [www.hta.gov.uk/guidance/licensing_guidance/expected_standards.cfm].
44. Although the HT Act is silent on the use of photographic or electronic images, the HTA believes that it is good practice for consent to be obtained for the making and subsequent display of such images.

Obtaining consent

45. The giving of consent is a positive act. The fact that there is no evidence of refusal to consent does not mean that consent has been given. All those involved in the storage and use of human tissue, including its use for public display, must be satisfied that consent is in place.
46. Obtaining valid consent presupposes that there is a process in which individuals, and their relatives or close friends may discuss the issue fully, ask questions and make an informed choice.
47. A record of consent should be made, evidencing that the person giving their consent has full knowledge and understanding of what they are consenting to.
48. Anyone organising a public display of bodies or relevant material must have the necessary assurance that valid consent has been given, although they do not need to have taken or recorded the consent personally.

49. For the storage for public display or actual public display of a body, body parts or tissue from a deceased person, whether an adult or a child, consent must be given by the person in life. This means that the consent has to be signed by the person concerned, or at his direction and in his presence, and witnessed in either case, or stated in a legally made will. Neither the next of kin nor any other person can agree to the use of an individual's body after their death for public display.

Licensing

50. 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, 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 storage for the purpose of public display or the actual public display of bodies or relevant material from the deceased, but not from the living.
51. The HTA does not consider the display of bodies or relevant material to small professional groups 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 or relevant material which is delivered to the police or paramedics as part of their professional development, it is not considered public display.

52. Nor does the HTA consider the display of bodies or relevant material to students from a different establishment embarking on a career in healthcare to be public display

Example – Medical students beginning their first year of study are taken on a tour of the anatomy and pathology museum of a leading teaching hospital licensed by the HTA for storage of relevant material and 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.

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

Example – At a university open day, visitors are shown the lungs of both a smoker and 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 from people that 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.

54. As mentioned earlier, storage for the purpose of public display or the actual public display of body parts or tissue from a living person are not activities that require licensing. Establishments that are storing or publicly displaying relevant material from the living do not require a licence 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.

55. Bodies or relevant material from the deceased imported into the UK for the purpose of public display are subject to licensing by the HTA.
56. 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 HTA's code of practice on import and export for further guidance.

57. The 'existing holdings' exemption to the consent requirements of the HT Act does not apply to the licensing requirement.

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 the purpose of public display and for public display is required.

Material over 100 years old

58. 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.
59. Some museums hold collections where the age of the material is unknown. Where investigations are inconclusive and it is uncertain whether the material is over 100 years old or not, the earliest known acquisition date will be taken as an indicator of the age of the material. Where no acquisition date is available, an HTA licence should be applied for.

Example – A national museum obtained a large number of preserved human organs in the 1950s from a hospital museum that was being closed down. It has records of when the hospital museum obtained the exhibits but is unsure when the patients died. Some of the exhibits were obtained by the hospital museum in the 1930s and 1940s but it is believed the donors died more than 100 years ago. At present, the museum has no plans to display any of the exhibits that were obtained less than 100 years ago. As there are no records to confirm when the people died, the museum must rely on the acquisition dates from the hospital museum, and in accordance with the HT Act, a licence for the storage of this material for scheduled purposes is required even if the exhibits are not on public display.

Loans to other museums

60. The HT Act does not allow the loan of items or collections from a licensed establishment to a non-licensed establishment (this arrangement applies only to specimens donated for 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.
61. Where material is moved between licensed establishments, there should be a documented loan agreement, which sets out the steps taken to ensure safe handling of the material, any environmental controls required and procedures to deal with adverse events such as damage to the material or a breach of security.

'Under 20 items' rule

62. Some museums hold very small collections, for example comprising a single skeleton or a small number of organs. Where fewer than 20 items are stored or displayed, a reduced licence fee applies.

Example – A music school displays a preserved hand from the school's founder, a famous pianist. The founder specifically asked for it 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 hand, in line with the founder's wishes. The music school has less than 20 items and the reduced licence fee applies.

Licensing and photographic / electronic images

63. As mentioned earlier, the HT Act is silent on the use of photographic or electronic images so a licence is not required for the public display of photographs containing images of bodies or relevant material, or for broadcast images, for example on television.

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 broadcast are outside the remit of the HTA. However, the viewing of the dissection by an audience, 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 if the body is that of a person who died after the commencement of the HT Act, consent for their body to be used for public display has to have been given by the person before they died.

Licensing standards

64. In order to obtain a licence from the HTA, an establishment must demonstrate that it meets a number of core standards relating to the consent provisions of the HT Act, the governance and quality systems that are in place, the premises and facilities and the arrangements for disposal. These standards are complementary to those of the Museums Licensing Association (MLA's) Accreditation Scheme for Museums in the United Kingdom [www.mla.gov.uk/website/programmes/accreditation].
65. The person with statutory responsibility under the HT Act, the Designated Individual (DI), has a duty to ensure that suitable persons following suitable practices are carrying out the licensed activities and that the conditions of the licence and the licensing standards are complied with. The HTA standards are designed to help DIs fulfil this statutory duty.
66. The HTA codes of practice on Consent and Disposal of human tissue offer advice and guidance on how to meet the requirements of the HT Act and licensing standards in these areas. Help in understanding the requirements relating to the HTA standards on governance and quality systems and premises, facilities and equipment is contained in the following paragraphs.

HTA standards for public display

67. The standards were developed in consultation with representatives from the sector, and reinforce the intentions of the HT Act that consent is paramount when engaged in activities involving the use of relevant human material, that the bodies of the deceased and tissue taken from bodies should be treated with respect and that the dignity of the person should be maintained.

Governance and quality systems

68. The HTA standards on governance and quality focus on the internal systems and processes that are in place to support staff in the delivery of high quality services.
69. Staff may have worked in the same establishment for many years, and may not have taken time to reflect on their practice. The HTA regulatory process allows all those involved in the public display of relevant material the opportunity to reflect on their practices, review their procedures and make improvements where areas of deficiency are identified.
70. The work of the staff at the establishment undertaking a public display or storing for public display should be subject to a system of governance. That means that there should be clear reporting lines and accountability, documented roles and responsibilities, a system of staff appraisal, training and development and standards of professional practice.
71. All staff working under the licence should be involved with governance meetings at some level, even if the core team is small. Team meetings provide an ideal opportunity to pass on relevant information to staff working under the licence, as well as allowing them to raise any issues or concerns. Minutes should be taken and made available to all relevant staff.
72. There should be documented policies and procedures covering all aspects of storage and public display. These should be up to date, subject to regular review and reflective of good practice, including guidance from professional bodies such as the MLA and the DCMS.
73. Where appropriate, procedures should be developed in consideration of potential risks. For example, where staff undertake cleaning of material on public display, the procedure should be based on the assessment of risk to staff from contamination and the cleaning materials they will be exposed to, as well as the potential risk of damage to the item being cleaned.
74. For risk assessments to be meaningful they should be undertaken by a suitably trained person, who has an objective view, or whom is following an established risk assessment process. It may not be appropriate for staff

working under the authority of the licence to undertake their own risk assessments. In any event, the results of risk assessments should be shared with staff so that they have an understanding of the issues identified.

75. The HTA inspectors will want to assure themselves that there is an understanding of and commitment to continuous quality improvement, evidenced by a programme of audit, and that staff are given training and development opportunities to update their skills and ensure that their practices reflect current thinking in the sector.
76. Access to advice and guidance from organisations such as the HTA, the Health and Safety Executive [www.hse.gov.uk/], the Health Protection Agency [www.hpa.org.uk/] and the MLA should be freely available, and there should be commitment from management to provide the means by which improvements can be made. For example, establishments may wish to encourage their staff to join the relevant professional body and provide the ability to access the professional body's website during working hours.
77. As mentioned earlier in this code, appropriate consent for public display is essential. An establishment must keep records that document consent and facilitate traceability of the material stored or displayed. The procedures relating to indexing and record-keeping should reference the establishment's system of labelling bodies and body parts.

Example – An establishment has assigned a unique number to each body part stored or used for the purpose of public display. This number is recorded alongside the deceased's name and consent for public display forms. This system allows for easy traceability from consent to body part.
78. 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.
79. The DI should be aware of the need to ensure the safety of people viewing a public display as well as of staff working at the establishment. This should be covered by a documented risk assessment.
80. All establishments licensed by the HTA are expected to have a system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis. In a public display environment, the focus is usually on health and safety, for example trips and falls. With the statutory requirements the HT Act imposes, a re-evaluation of the definition of an adverse event should be considered by DIs, giving attention to incident or events that may impact on the establishment's ability to meet the requirements of the HTA codes of practice and licensing standards. Also, consideration should be given to the security and integrity of relevant material. The HTA inspectors will seek

to assure themselves that staff working under the licence understand what is meant by an adverse event and are familiar with the procedure to follow when such an event occurs. Adverse events classified by the DI as severe in nature should be reported to the HTA.

Premises, facilities and equipment

81. Establishments storing or using relevant material for the purpose of public display may vary in size, age and condition. In extreme cases, the HTA will take regulatory action to prevent public display taking place in premises considered to be unsuitable. However, this is an undesirable outcome. The HTA seeks to work with establishments through its inspection process, to help them make improvements where improvements can be made, and takes a proportionate and risk-based approach where scope for improvement has been exhausted.
82. Premises must be 'fit for purpose'. This means that areas used for storage or public display must provide an environment that is safe for staff and visitors and preserves the integrity of the material.
83. Relevant material should be preserved, stored and displayed in such a way that it minimises the risk of contamination to staff and visitors. If necessary, the DI should also put in place environmental controls and appropriate equipment to reduce the risk of contamination.
84. The DI should also consider risks to the material, such as theft or damage. Security measures should include the use of lockable display areas, alarm systems and indelible identification marking of relevant material if appropriate. Consideration should also be given to mitigating damage from visitors, humidity, UV light, temperature extremes and pests. For example, storage and display environments may require continuous temperature monitoring and heating and cooling systems.
85. As advised in the DCMS Guidance for the Care of Human Remains in Museums [www.culture.gov.uk/NR/rdonlyres/0017476B-3B86-46F3-BAB3-11E5A5F7F0A1/0/GuidanceHumanRemains11Oct.pdf], visitors to a public display of relevant material should not come across human remains unawares. The establishment should give consideration to suitable signage, explaining the presence of bodies and / or body parts or other relevant material and the requirement to treat them with dignity and respect.
86. Consideration should be given to the layout of the public display area to reduce or eliminate a risk of contamination from relevant material and provide a suitable and safe environment for visitors to view the display.
87. Where chemicals are used for preservation, the area must be adequately ventilated to control exposure. COSHH [www.hse.gov.uk/coshh/] requires the exposure of formaldehyde to be controlled as low as possible and below the

maximum exposure limit (2 pm). This may include monitoring of levels and continuous operating extract ventilation.

88. There should be clear demarcation of 'clean' and 'dirty' preservation areas.
89. The establishment should be clean, well maintained and subject to a programme of planned preventative maintenance.
90. Staff should have access to the protective clothing, materials and equipment they need. Equipment should be regularly maintained to ensure that it is suitable for use. Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining. There should be a system for renewing items that are no longer suitable through wear and tear.
91. Preservation staff should be aware of and have access to guidance from the HSE [www.hse.gov.uk/] on safe working and the prevention of infection.
92. If relevant material is loaned to or borrowed from another licensed establishment, consideration should be given to minimising the likelihood of theft or damage during transport. Loan agreements should define how the material is preserved and any potential contamination risks associated with it. There should be clear instruction on how to deal with an adverse event and contact details for the responsible person at the establishment loaning relevant material.
93. The establishment should have contingency arrangements in place should there be an emergency situation that renders the premises unsuitable for the storage or display of relevant material.
94. Finally, the HTA expects compliance with all its standards, even if the public display of relevant material is to be held only for a short period of time or if only a few items are held under the authority of a licence.
95. The HTA has published a Guide to licensing for Designated Individuals and Licence Holders, which sets out in detail the licensing arrangements under the HT Act [[link](#)]. Included is a description of the role of the Designated Individual, which is of fundamental importance to the HT Act's scheme of regulatory control and the HTA's licensing framework.

Appendix A

Scheduled purposes and licensing

A1. To understand fully the requirements of the HT Act, knowledge of scheduled purposes and licensable activities is required.

A2. 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

A3. There are three scheduled purposes which relate to the public display sector; consent is required for all of these purposes.

- i. public display, which applies to material from the living and deceased
- ii. research in connection with disorders or the functioning of the human body, which applies to material from the living and the deceased
- iii. education or training relating to human health, which applies to material from the deceased only

A4. Note that only (i.) above requires consent from the deceased person in life; consent for the scheduled purposes detailed in (ii.) and (iii.) can be provided by the deceased person's nominated representative or next of kin (refer to the code of practice on Consent for more information).

Licensable activities

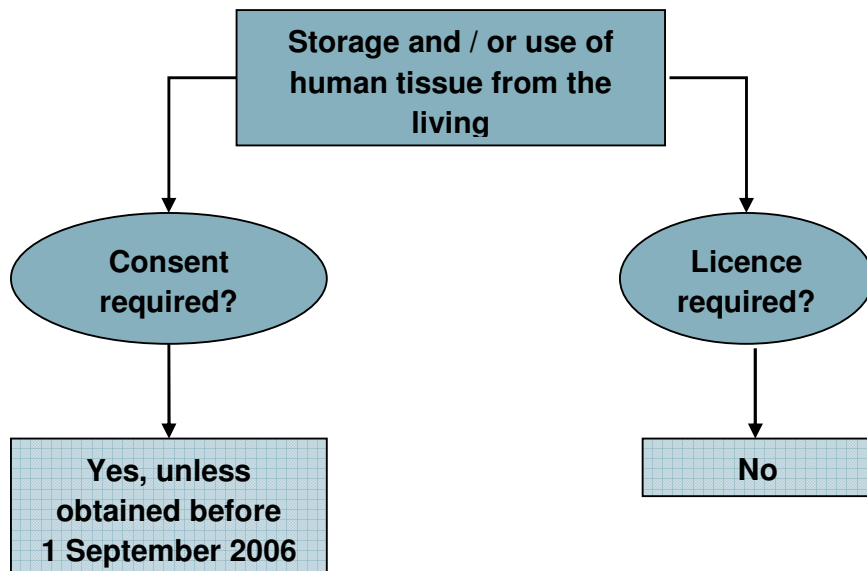
A5. There are two licensable activities which are relevant to the public display sector:

- i. the use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person
- ii. the storage of the body of a deceased person, or relevant material which has come from a deceased person, for a scheduled purpose

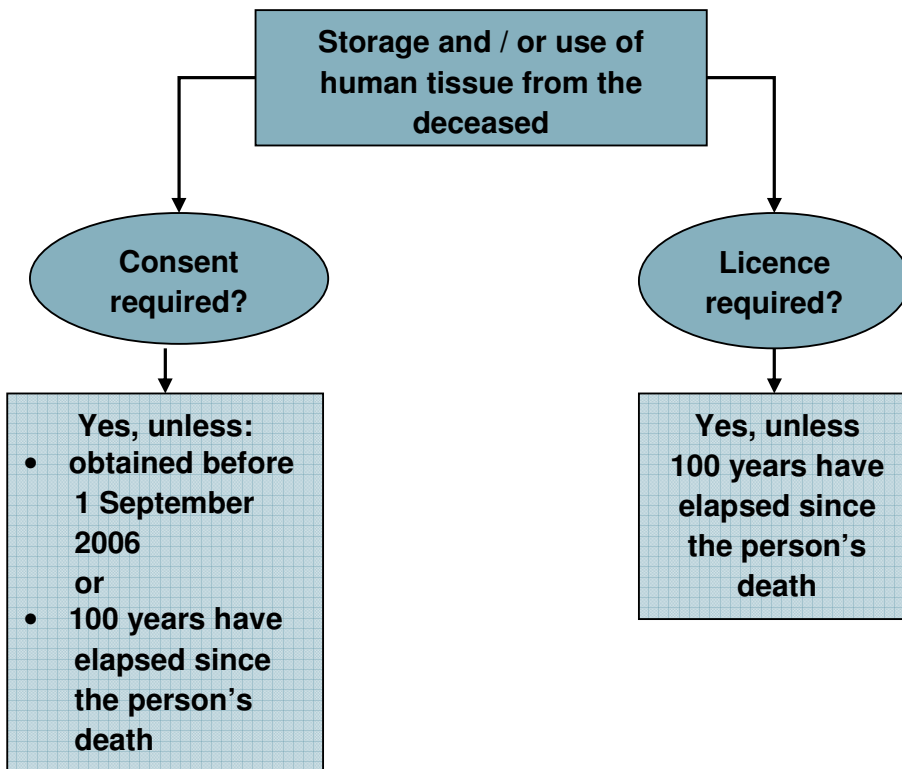
A6. That means that a licence is not required for the storage or public display of body parts or tissue from the living.

Appendix B: Licensing and consent flowcharts

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



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



References

Guide to licensing for DIs and LHs

www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm

Guidance on applying for a licence

www.hta.gov.uk/licensing/guide_to_licensing_and_application.cfm

Model consent forms [/www.hta.gov.uk/guidance/model_consent_forms.cfm](http://www.hta.gov.uk/guidance/model_consent_forms.cfm)s

E-learning training course for DIs

www.hta.gov.uk/licensing/designated_individuals_and_licence_holders.cfm

Department for Culture Media and Sport (DCMS) Guidance for the care of human remains in museums www.culture.gov.uk/NR/ronlyres/0017476B-3B86-46F3-BAB3-11E5A5F7F0A1/0/GuidanceHumanRemains11Oct.pdf

Museum Association's Code of Ethics

www.culture.gov.uk/NR/ronlyres/0017476B-3B86-46F3-BAB3-11E5A5F7F0A1/0/GuidanceHumanRemains11Oct.pdf
<http://www.museumsassociation.org/ma/10934>

General Medical Council, Making and using visual and audio recordings of patients www.gmcuk.org/guidance/current/library/making_audiovisual.asp#1

Museums Licensing Association Accreditation Scheme for Museums in the United Kingdom www.mla.gov.uk/website/programmes/accreditation

Control of Substances Hazardous to Health (COSHH) www.hse.gov.uk/coshh/

Health and Safety Executive www.hse.gov.uk/

Health Protection Agency www.hpa.org.uk/

Glossary

Accredited Assessor: A person trained and accredited by the HTA to act as a representative of both the donor and the HTA to ensure the relevant requirements of the HT Act and HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 are met, in cases of potential bone marrow or PBSC donations.

Anatomical examination: Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body

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 him immediately before he died.

Bone marrow: The soft, spongy tissue found in the centre of most large bones that produces the cellular components of blood: white cells, red cells and platelets.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue. For establishments licensed for human application this includes cell lines grown outside the human body but not gametes, embryos outside the human body, or blood and blood components.

Designated individual (DI): The individual designated on the licence to supervise the licensable activities carried out. DIs are trained by the HTA to carry out this important role and they have statutory responsibilities they must fulfil.

Diagnosis: A process where a disease is identified.

Donation: The act of donating 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.

Existing holdings: The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to the commencement of part 1 of the HT Act 2004.

Human Application: In relation to tissue or cells, means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use for autologous graft (tissue or cells removed from and applied in the same person within the same surgical procedure).

Independent Assessor: A person trained and accredited by the HTA to act as a representative of both the donor and the HTA, to ensure the relevant requirements of the HT Act and HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 are met, for certain types of living organ transplantations

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

Licence holder: The person who holds a licence and is responsible for the payment of any fees charged by the HTA. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 the Licence Holder is also responsible for complying with HTA Directions. The Licence Holder can be a corporate body. Where the applicant is not the proposed Designated Individual, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

Nominated representative: A person appointed by a deceased person who is empowered to consent to the carrying out of a post mortem examination and 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 HT Act (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. A differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy.

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. A hospital post-mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post-mortem examinations are carried out under the authority of the coroner and without consent to assist coroners in carrying out their functions. See also minimally invasive autopsies and non invasive autopsies.

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 website [www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm].

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 of new knowledge.

Scheduled purposes: Scheduled purposes specify where the use of relevant material requires consent. In addition, the licensed activities of removal and storage relate to scheduled purposes. The purposes are divided into 2 parts:

Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person's death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation.

Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance.

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

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: Is consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.