



Human Tissue Authority

Code of practice 4 Anatomical examination

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Introduction

The legislation and the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1 covers England, Wales and Northern Ireland. The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1.
2. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) www.opsi.gov.uk/si/si2007/uksi_20071523_en_1 implement the European Union Tissue and Cells Directives (EUTCD). The HTA is a Competent Authority in the UK under the Q&S Regulations, which cover the whole of the UK, including Scotland.
3. The HTA's remit in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 (Ref: NHS HDL (2006) 46) http://www.hta.gov.uk/db/documents/Information_about_HT_%28Scotland%29_Act.pdf and the relevant codes of practice. Relevant guidance from Wales and Northern Ireland is referenced throughout the codes.

About the codes of practice

4. 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.
5. The codes are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA's website.
6. 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](#)
7. All nine codes of practice have been brought into force by HTA Directions www.hta.gov.uk/guidance/licensing_guidance/expected_standards.cfm.

Using the codes

8. In these codes, the word '**must**' refers to an overriding duty or principle, including all specific legal requirements derived from primary and secondary legislation – for example, the requirement to hold a licence to store human tissue for a scheduled purpose.
9. We use the word '**should**' when explaining how to meet the specific legal requirements. Establishments are expected to follow the guidance in the codes. Observance of the guidance in the codes is one of the ways in which the HTA assesses that establishments are complying with relevant legislation. Failure to follow a code of practice is not in itself a criminal offence under the HT Act but the HTA will carefully consider any breach of a code of practice and may take appropriate regulatory action.
10. The codes 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. A glossary with terms specific to each code is available at the end of each document, and a full list of glossary terms is on the HTA's website.
11. You can download and print copies of the codes from the HTA's website www.hta.gov.uk/guidance/codes_of_practice.cfm.

Other advice and guidance

12. 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. Professional guidelines have been drawn up by the Professional Guidelines and Practices (Anatomy) Committee and are available on the websites of three professional bodies which comprise the committee, namely: Anatomical Society of Great Britain and Ireland (ASGBI), www.anatsoc.org.uk, British Association of Clinical Anatomists (BACA) www.liv.ac.uk/HumanAnatomy/phd/baca/ and Institute of Anatomical Sciences (IAS) www.anatomical-sciences.org.uk. The HTA's codes of practice and other 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.

Scope of this code

13. The HT Act permits, with consent, the donation of whole bodies for anatomical examination. It also allows for the storage and anatomical examination of a body, provided that it is carried out by, or under, the direction of a Designated Individual (DI) , with consent, and providing that the death has been properly certified and registered.

14. This code provides guidance for people working in the anatomy sector and sets out the standards that establishments must meet in order to hold a licence to carry out anatomical examinations or to store anatomical specimens.

Status of this code

15. Anatomical examination falls within the HTA's statutory remit. This code on Anatomical examination replaces the previous code of practice. In accordance with Section 29 of the HT Act, it has been approved by the Secretary of State following consultation with the Welsh Assembly Government and the relevant Northern Ireland department, and it has received Parliamentary approval.

Providing information to potential donors

16. 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 or oral) so that donors may choose which is most appropriate for them. Information is also provided for potential donors on the HTA's website www.hta.gov.uk/about_hta/donating_a_body_to_medical_science.cfm.

17. The HTA has produced a model bequeathal booklet and a model body donation consent form to aid anatomy establishments www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/anatomy_schools.cfm.

Obtaining appropriate consent

18. 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.

19. For consent for body donation to be valid under the HT Act, it must be in writing and:

- signed by the donor in the presence of at least one witness who attests their signature; or
- signed by a representative at the direction of the donor, in their presence and in the presence of at least one witness who attests the representative'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 representative to sign on behalf of a donor www.hta.gov.uk www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/anatomy_schools.cfm In these circumstances, the HTA advises that:
 - 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
 - the representative should sign their own name, state that they have signed at the direction of the donor and explain the circumstances of this direction
 - the form should then be signed by a third party 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: 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 local medical school.

20. Documented and valid consent for anatomical examination given before 1 September 2006 is treated as appropriate consent under the HT Act.

21. Under the HT Act, appropriate consent is not needed for removal, storage and use of material from a deceased body for anatomical examination, if more than 100 years have elapsed since the date of the person's death. Appropriate consent is also not needed if the body has been imported. The import and export of bodies or body parts is discussed in paragraphs 61–63 of this code.

22. Anyone wishing to donate their body, or part of their body, for anatomical examination should preferably use a consent form, which should be kept as part of the donation records. The HTA has produced a model body donation consent form www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/anatomy_schools.cfm.

23. Individuals may indicate their choice to donate their bodies for anatomical examination in their will. In this case, an individual should be encouraged to fill in a consent form from their nearest medical school and to insert a copy in their will. The body donor should be made aware that, although a consent form does not have to be used in their will, 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.

24. 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.

25. Storing a body for anatomical examination is lawful provided that:

- there is appropriate consent; and
- 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.

This allows establishments to proceed to storage and timely preservation of a body donated for anatomical examination, if registration of death has been delayed.

26. Using a body for anatomical examination is lawful provided that :

- there is appropriate consent; and

- the person's death has been registered.

Licensing

27. Detailed guidance about the licensing framework is outlined in the HTA Guide to licensing for Designated Individuals and Licence Holders www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm .

Existing anatomical specimens

28. Under the Anatomy Act 1984, anatomical specimens could only be used for anatomical examination during a period of three years from the date of the person's death. The HT Act provides for situations where material donated under the Anatomy Act 1984 was being held by anatomy establishments at the time the consent provisions of the HT Act came into force on 1 September 2006.

29. In relation to donations made under the Anatomy Act 1984 by people who died between 1 September 2003 and 31 August 2006, the HT Act states that:

- if anatomical examination had not been completed by 1 September 2006, the authority given under the Anatomy Act 1984 for anatomical examination can be treated as appropriate consent for storage and use for anatomical examination under the HT Act for three years from the date of a person's death or until the anatomical examination is completed, whatever is the shorter period; and
- if anatomical examination is completed after 1 September 2006 but within three years of the person's death, authority given under the Anatomy Act 1984 to retain body parts can be treated as appropriate consent under the HT Act for their storage or use for research or education or training.

Documentation and record keeping

- 30.** All places where anatomical examination is carried out should keep records in a permanent form for each body or body part in their 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.
- 31.** Records relating to body parts retained after anatomical examinations have been concluded 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.
- 32.** All records must be available for inspection and review.

Care of cadaveric material

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

Example: A university anatomy establishment provides teaching to hundreds of healthcare students each year, some of whom attend from other universities. The DI is concerned that there is a risk that the dignity of deceased people may not always be upheld. She acknowledges that physical supervision of all students at all times would be impossible but wants to put safeguards in place to avoid the risk of occurrence of such an event. After thorough discussions with the establishment's staff, the DI puts a number of new safeguards in place, including:

- a review of the security of the premises
- a registration system, utilising a signing-in book so that the DI and other persons working under an 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
- revising the local code of conduct to reflect the requirements of the HT Act and the HTA code of practice on Anatomical examination
- a declaration to be signed by all relevant visitors to confirm that they have read and understood the local code of conduct
- prominent signs relating to important aspects of the local code of conduct

Transfer or loan of cadaveric material

- 55.** 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.
- 56.** Bodies or body parts may only be transferred or loaned for purposes for which consent was originally given.
- 57.** 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.
- 58.** Records should be kept of any loans, including relevant details of:
- the specimen/s covered by the agreement
 - the person authorised to hold the specimen/s
 - the address where the specimen/s will be held
 - the purpose for which the specimen/s is / are being moved
 - the purpose for which the authorised person may have possession of the specimen/s
 - the period for which the loan is so authorised
- 59.** The HTA has produced a model authorisation form for loan of anatomical specimens www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/anatomy_schools.cfm .
- 60.** The DI remains responsible for the material for the duration of the loan. The HTA advises that the borrower agrees to comply with the HT Act and code of practice on Anatomical examination and that storage is appropriate.

Example: 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 the HTA's code of practice on Anatomical examination 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.

Import and export of bodies or body parts

61. 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.

62. Imported material should be obtained, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. 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.

63. The import and export of relevant material is discussed in detail in the [code of practice on Import and export of human bodies, body parts and tissue](#).

The use of images

- 64.** 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.
- 65.** 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 http://www.gmc-uk.org/guidance/current/library/making_audiovisual.asp .
- 66.** Ensuring suitable practices where licensable activities are concerned includes the DI ensuring that the dignity of deceased people is maintained at all times. Therefore, DIs need to put in place systems to prevent the inappropriate use of images.

Charging

67. Charges may be applied to cover the costs of transporting and embalming bodies and of preparing retained parts for use at other establishments. These charges should fairly reflect the costs involved.

Glossary

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

Cadaver: The body of a deceased person.

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.

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.

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.

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.

Licensed premises: Where the licensed activity takes place. If the licensed activity will take place at more than one place, a separate licence will need to be issued for each place. Premises in different streets or with different postal codes will be considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

Relevant material: Defined by the HT Act as material other than gametes, which consists of or includes human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm .

Scheduled purposes: Under the provision of the HT Act consent must be obtained to remove, store or use bodies or relevant material for 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.

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

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

HTA standards

- 33.** The HTA has developed a number of standards, with which establishments must comply. These standards were developed in consultation with representatives of the anatomy sector. They reinforce the intention of the HT Act that consent is paramount for activities involving the use of human tissue; that dead bodies, and tissue taken from them, should be treated with respect; and that the dignity of the person maintained at all times.
- 34.** The HTA standards are grouped under the headings: Consent (C); Governance and quality systems (GQS); Premises, facilities and equipment (PFE); and Disposal (D).
- 35.** The following sections give guidance on HTA licensing standards. Specific guidance on consent is given in [paragraphs 18–26](#) of this code.

Governance and quality systems

- 36.** The GQS standards focus on internal systems and processes that are in place to support staff in the delivery of high quality services.
- 37.** As part of the overall governance process, the HTA requires that all aspects of an establishment's work are supported by ratified, documented policies and procedures. Documents should be ratified by a process involving more than one person and be subject to scheduled review.
- 38.** A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained.
- 39.** Meetings relating to licensable activities should be supported by an agenda and minutes, and establishments should have a system for dealing with complaints from the public and other users.
- 40.** The HTA requires establishments to have a documented quality management system in place. This does not need to be electronic, however, it should include a document control system, covering all documented policies and procedures.
- 41.** The HTA requires DIs to ensure that all staff working under the authority of an HTA licence are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. Staff training records should show qualifications, courses attended, evidence of attendance at induction and orientation training, evidence of recurrent appraisal and a personal development plan.
- 42.** The HTA requires establishments to have a systematic and planned approach to the management of records, including documented procedures for the creation, amendment, retention and destruction of records. Record content should be audited regularly to ensure completeness, accuracy and legibility. Computerised records should be backed up and a system for data recovery should be in place. Data protection and confidentiality should be key components of the records system.
- 43.** The HTA requires establishments to use a coding and records system that facilitates the traceability of bodies and separated parts, ensuring a robust audit trail.
- 44.** The HTA requires that establishments have systems in place to ensure that all adverse events are investigated properly, and corrective and preventative actions are taken when necessary, to ensure that improvements in practice are made.
- 45.** The HTA encourages establishments to advise it of serious incidents which adversely affect compliance with the HT Act and this code of practice.
- 46.** The HTA requires that documented risk assessments of establishments' practices and processes are completed regularly and are subject to scheduled review. Staff members should be able to access the risk assessments relevant to their work and be made aware of local hazards.

Premises, facilities and equipment

- 47.** The HTA requires that premises are secure and appropriate for the purpose for which they are used. This means that a risk assessment should have been undertaken and that there are policies in place to review and maintain the safety of staff, authorised visitors and students. Policies to ensure that the premises are maintained to a standard that ensures the dignity of the deceased should be in place, as should policies to ensure that confidentiality is maintained.
- 48.** DIs should ensure that suitable environmental controls are in place to avoid potential contamination. Documented cleaning and decontamination procedures should be in place and staff should be provided with appropriate personal protective equipment. Air quality and safe environmental conditions should be suitably maintained and appropriately monitored.
- 49.** The HTA requires that establishments have appropriate facilities for the storage of cadaveric material, consumables and records; including a requirement that precautions are taken to minimise damage or theft.
- 50.** The DI is responsible for the body and body parts of the deceased from the time of donation until the burial, cremation, disposal or return to the family. The HTA requires the DI to put in place documented policies and procedures for the transport of cadaveric material, including a risk assessment. Full traceability should be ensured during transportation; records of transportation and delivery should be kept. Records

should also be kept of any transfer agreements with recipients of relevant material and of any written agreements with couriers or transport providers.

51. Equipment should be appropriate for use and documented contingency arrangements should be in place in case of equipment failure. Calibration, validation and maintenance records should be kept, along with any written agreements with maintenance companies. Equipment users should have access to reliable instructions and receive training in safe use and maintenance where appropriate. Additionally, staff should be made aware of how to report equipment problems.

Disposal

52. The DI of an establishment which accepts a body must ensure that robust and appropriate systems are in place for its storage, examination and preservation until after cremation or burial occurs or the body is returned to the family.

53. 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 see the code of practice on Disposal of human tissue. Where possible, these practices should be explained to the donor at the start of the donation process.

References

References are listed in the order in which they appear in the code. Supplementary references are included at the end.

[Human Tissue Act 2004](#)

[Human Tissue \(Scotland\) Act 2006](#)

[The Human Tissue \(Quality and Safety for Human Application\) Regulations 2007](#)

[Human Tissue \(Scotland\) Act 2006: A guide to its implications for NHS Scotland issued on 20 July 2006 \(Ref: NHS HDL \(2006\) 46\)](#)

[HTA codes of practice](#)

[HTA Directions](#)

[The Anatomical Society of Great Britain and Ireland \(ASGBI\)](#)

[British Association of Clinical Anatomists \(BACA\)](#)

[Institute of Anatomical Sciences \(IAS\)](#)

[HTA guidance on donating your body to medical science](#)

[HTA guidance for anatomy establishments](#)

[HTA guide to licensing for DIs and LHs](#)

[General Medical Council \(GMC\) guidance Making and using visual and audio recordings of patients](#)

Supplementary references

[HTA guide to licensing and application](#)

[E-learning training course for DIs](#)

[Welsh Language Act](#)

[HTA summary inspection reports](#)

[HTA guide to our key messages](#) - which explains the HTA's roles and responsibilities

[HTA e-newsletter](#) – which provides regular news and updates about the HTA's work