



The Royal College of Pathologists
Pathology: the science behind the cure

Questions and answers:

The Human Tissue Act 2004

October 2006, revised September 2007

Note: This document will not answer every question and it may contain errors. The intention is for it to be a 'dynamic' document, regularly updated and corrected. If you believe that any of the information provided in this document is incorrect, please contact the College Publications Department, email publications@rcpath.org explaining the error/s and supplying supporting evidence, preferable in the form of a reference to the legislation or to advice provided by the Human Tissue Authority (HTA).

We hope that in time, all the questions in this document will become redundant. If you believe any of the information in this document is a duplicate of information on the HTA's website, let us know and we will delete the item and replace with a link to the HTA's website.

If you have a question that is not answered from any source, please contact Professor Peter Furness, email pnfl@le.ac.uk

Disclaimer: This document is provided in good faith, but the Royal College of Pathologists cannot accept liability for any breach of the law arising as a result of this guidance.

Sources of authoritative information

The definitive source of information is the text of the Human Tissue Act (2004) available at www.opsi.gov.uk/acts/acts2004/20040030.htm

Some of the provisions of the Act have since been modified by ministerial directives, most notably in relation to:

- requirements for licensing - www.opsi.gov.uk/si/si2006/uksi_20061260_en.pdf
with an explanatory note - www.opsi.gov.uk/si/em2006/uksiem_20061260_en.pdf
- procedures in relation to persons unable to give appropriate consent -
www.opsi.gov.uk/si/si2006/uksi_20061659_en.pdf
with an explanatory note - www.opsi.gov.uk/si/em2006/uksiem_20061659_en.pdf

For Scotland, the Human Tissue (Scotland) Act 2006 is available at www.opsi.gov.uk/legislation/scotland/acts2006/20060004.htm

This Q&A does not cover the Scotland Act.

Unfortunately these definitive sources of information are phrased in legal language which most pathologists find somewhat impenetrable.

Apart from the legislation itself, the most authoritative source of advice can be obtained from The Human Tissue Authority (HTA). The HTA has updated its website at www.hta.gov.uk

The HTA provides an extensive and far more easily comprehensible source of information on the Act, together with their interpretation of the areas which the Act leaves in the domain of the Authority.

The Human Tissue Authority website, and not the College website, should therefore be used as the first source of information about the interpretation and implementation of the Act.

What activities need a Human Tissue Authority licence?

The Human Tissue Act defines a set of activities which need a Human Tissue Authority license. These are:

- the carrying out of an anatomical examination
- the making of a post-mortem examination
- the removal from the body of a deceased person (otherwise than in the course of the activities mentioned above) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose other than transplant
- the storage of an anatomical specimen
- the **storage** (other than of an anatomical specimen) **of** the body of a deceased person or relevant **material which has come from a human body for use for a Scheduled Purpose**
- 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.

The words in bold text (our emphasis) in the fifth bullet point seem to have caused most concern for members of the College.

Exemptions to the licensing requirements have been extended by Ministerial regulation. (www.opsi.gov.uk/si/si2006/uksi_20061260_en.pdf Section 3):

“In relation to tissue from living persons, the exemptions from licensing include storage for determining the cause of death, establishing after a person’s death the efficacy of any drug or treatment administered to him, obtaining information which may be relevant to another person, public display, clinical audit, education or training relating to human health, performance assessment, public health monitoring, quality assurance and ‘qualifying research’ (in essence, ongoing REC-approved research projects)”

An explanation in non-legal language is on the HTA website

www.hta.gov.uk/guidance/licensing_guidance/licensing_and_consent_exemptions.cfm

Consequently, the only common uses of human tissue *from the living* where a licence is still required for storage is when the storage is for future, unspecified research projects, that is, storage in a ‘research tissue bank’, or storage (for more than 48 hours) for transplantation.

Tissue stored for an ongoing REC approved project (or where an application for ethical approval has been submitted) does not need a licence. So what happens when the project ends?

A research licence will be required by any institution which holds samples for future research, other than in on-going REC approved projects.

An institution’s research storage licence may be able to cover many small separate collections, but only if the Designated Individual is aware of the collection and all of the licence’s Conditions are satisfied.

So when a research project is completed, any tissue samples left over must in some way be covered by a licence, or they must be destroyed. **Please remember that the unnecessary destruction of samples that patients have donated for research is immoral.** If the residual samples have potential for use in future research projects, they should be lodged in a research tissue bank.

It has been argued that some samples (e.g. stained microscope slides) have to be retained by the research group after the project is complete as part of the ethical obligation to maintain records of the research, to allow future inspection and thereby to combat scientific fraud. This is likely to be acceptable for material where the only foreseeable future use is in such an audit, e.g. stained microscope slides. They are then being retained for audit, not research, so a storage licence would only be needed if they were of post-mortem tissue. This argument is unlikely to be an acceptable justification for the retention of blocks of tissue.

NHS archives are stored for the benefit of the patient whose body made the tissue, so they don't need a licence. Does that mean that samples from such archives can never be used in research?

No. The Department of Health and the Human Tissue Authority have agreed that the occasional, unplanned research use of samples from an unlicensed archive will not need a research storage licence, because the 'primary purpose' of the archive is not storage as a research tissue bank.

(Please remember that the 'primary purpose' test applies to every sample in an archive, not the archive as a whole. So if a diagnostic archive contains just one sample which is stored primarily for research use, a research storage licence would be needed).

However, exactly how much research use of NHS archives is allowable without a licence remains unclear. Teaching hospitals may need to seek HTA advice.

COREC has a new proposal to allow ethical approval of research tissue banks which would then allow samples from such a bank to be used in some simple research projects without further ethical review, see www.corec.org.uk/applicants/index.htm If an NHS archive was to be ethically approved in this way, we suspect that a HTA research license would probably be required to cover the archive.

Can specimens from a licensed collection be sent to an unlicensed site for analysis, and stored there?

Yes, briefly. However, the samples should be tracked by the licensed store. If any material is left over after the analysis is complete it should be returned there as rapidly as is practicable, or disposed of if the licensed site has indicated that this is acceptable.

Can specimens be acquired by an un-licensed site for the benefit of a licensed site?

This potentially applies to samples collected in non-academic units, from the living or the dead, for the benefit of a research tissue bank.

Storage which is incidental to transportation is acceptable. The law does not state for how long such storage outside licensed premises is acceptable, but the HTA has indicated that such batching and storage is acceptable as long as reasonable attempts are made to minimise the delay in transfer.

In one context a time limit of 48 hours has been suggested, but this is HTA interpretation, not a duration set out in statute. We have heard arguments that a 48 hour limit is sometimes impractical. For example, if samples are received late on Friday, transport would have to be arranged over a weekend. In such circumstances we suggest that you arrange transfer as rapidly as is practicable, but also inform the HTA of the problem, explaining how you are doing your best to comply with the spirit of the Act. If the HTA was to respond indicating that such storage is not acceptable, you would have to comply.

Can (or should, or must) existing collections of post mortem material now be disposed of?

The Department of Health lifted the moratorium on the disposal of existing holdings on 24 July 2006. Further information is available on the Department of Health website at www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tissue/fs/en

Disposal should take place in accordance with the Human Tissue Authority's Code of Practice on Disposal [www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament - Code of Practice 5 - Removal.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_5_-_Removal.pdf).

There is no compulsion to dispose of present holdings if there is some foreseeable useful purpose for the specimens.

The detailed advice cited above should be consulted. In brief:

- existing holdings that are unidentifiable under the criteria in the code and no longer required should be disposed of in the same way as other post mortem material is handled
- existing holdings that are identifiable and contact has been made by families should NOT be disposed of until relatives make their wishes clear
- it is legitimate for organisations to consider whether to dispose of existing holdings that are identifiable but no contact has been made by families. Organisations should allow 12 months from 24 July 2006 before taking any action, and those planning to dispose of such holdings will need to consider what level of local publicity may be appropriate in the light of the size of the holdings and any action taken so far.

What should pathologists do if a coroner has completed his involvement in a death, but has not communicated the wishes of the relatives in relation to the disposal or retention of samples removed at post mortem (without consent) for the purposes of the coroner? (Answer revised by Professor Furness, September 2007)

The 2005 amendment to the Coroners rules (www.opsi.gov.uk/si/si2005/20050420.htm) instructs coroners to ask relatives to express their wishes, but there is no compulsion on the relatives to reply, and there is no clear compulsion for the coroner to transmit the information to the pathologist. Unfortunately, occasionally the pathologist is left without instruction.

The pathology laboratory is not expected to communicate directly with bereaved relatives in such circumstances; to do so in ignorance of any communications between the coroner and the bereaved relatives would risk generating confusion and possibly distress.

It is relevant that the Human Tissue Act's provisions relate only to storage and use of these samples for Scheduled Purposes, as defined by the Act. If specimens are being stored "to facilitate compliance with the wishes of relatives" (or even "for no purpose whatsoever"), then these purposes are not Scheduled Purposes and therefore the provisions of the Act are not breached.

Nevertheless, pathologists will not wish to keep such samples for ever. The Human Tissue Authority has indicated a procedure which will permit the disposal of tissue samples under such circumstances.

If instructions have not been received, but the Coroner's authority is believed to have ceased, the pathologist should write to the Coroner explaining the advice in paragraph 25 of the Human Tissue Authority Code of Practice 5, which relates to disposal of tissue ([www.hta.gov.uk/db/documents/2006-07-04 Approved by Parliament - Code of Practice 5 - Removal.pdf](http://www.hta.gov.uk/db/documents/2006-07-04%20Approved%20by%20Parliament%20-%20Code%20of%20Practice%205%20-%20Removal.pdf)). This states:

"Where (the relatives) ...have not expressed a preference by the time the coroner's time limit expires, the organs or tissue may be stored for up to six weeks. The relatives should then be advised that unless they specify otherwise, the organs or tissue will be disposed of in a further four weeks' time. "

The letter should indicate to the coroner that the wishes of the bereaved have not yet been communicated to the laboratory.

If after six weeks no instructions are received, the pathologist should write to the Coroner again and advise that after a further four weeks, if not advised to the contrary, the material will be disposed of.

If after the final four week period has elapsed the wishes of the relatives have still not been communicated to the laboratory by the coroner, the tissue may be disposed of in accordance with the Code of Practice cited above.

Do I need consent or a licence to store DNA for genetic testing?

Not as a result of the 2004 Act. This Act relates only to human tissue, which is defined as containing cells made by a human body. Consequently, once DNA has been purified from the tissue **for a legitimate purpose**, the Human Tissue Act is silent about its storage or use.

There are of course many other good reasons for obtaining consent before DNA analysis, whenever possible.

Do I need consent or a licence to store tissue or cells for genetic testing?

Probably, but there are certain exceptions. There is misunderstanding about this because before the Ministerial Regulations (see above) were introduced, the HTA website carried a simple statement:

“Both consent and a licence are needed to store any tissue or cells for the purpose of genetic testing – to protect family members.”

This is an over-simplification and has been withdrawn.

In practical terms, the most important exemption for consent and licensing in relation to tissue and genetic testing is where the testing is done for the benefit of the person whose body produced the tissue. This does not require consent under the 2004 Act (though obviously consent may be desirable or mandatory for other reasons). Storage for this purpose is not a licensable activity.

The Ministerial Regulations at www.opsi.gov.uk/si/si2006/uksi_20061260_en.pdf include an exemption from the licensing requirement for storage of tissue from living persons for the Scheduled Purpose of *“obtaining information which may be relevant to another person”* (Section 3(2)(a)); though, of course, the requirement for Appropriate Consent for this purpose is not altered.

Of course, if an archive contains just one specimen that is being stored for a purpose that still requires a licence, then a licence is required. The presence of any tissue obtained at post-mortem would therefore almost certainly incur the need for a licence, as would storage for DNA analysis in a research tissue bank. The Act contains an exemption for use and storage for DNA analysis in on-going REC-approved research projects that parallels the exemption for other types of research.

Do I need consent or a licence to store and use human cell lines?

If you create a cell line from human tissue, the Act applies to the creation of the cell line, because you are using human tissue; the answer to the question depends on many factors, notably the purpose of creating the cell line, as discussed elsewhere. But the Act applies only to human cells made by a human body. If the cells have been produced in tissue culture, the Act does not apply.

There have been discussions about how many passages are required before one can be confident that a cell line no longer contains any of the original cells in a non-dividing state. We are not aware of a satisfactory answer.

Is a licence needed to remove small urgent samples (e.g. for microbiology) immediately after death?

This question relates to the recommendation in the Kennedy report on unexpected infant deaths, which recommended taking certain samples as soon as possible after death has been confirmed, typically in the A&E department.

This sampling is now illegal unless the location in question is covered by a licence. Consequently, **wherever possible licences for mortuaries should be framed to cover A&E departments, wards, etc where such**

sampling might occasionally be needed. Where for geographical reasons this is not possible, staff should be aware that, at present, the body must be transferred to a licensed site before such samples can be taken.

Do I need a licence or consent to take photomicrographs?

The Human Tissue Authority's answer to this question has been to endorse the guidance of the General Medical Council, available at www.gmc-uk.org/guidance/library/making_audiovisual.asp

See paragraph 5 - consent is **not** required to take photomicrographs, but paragraph 6 emphasises that the patient must not be identifiable.

Paragraph 24 makes it clear that consent is **not** required for publication of such anonymised images. Once an image has been legitimately produced, it contains no tissue, so its further use is not regulated by the 2004 Act; but there are of course numerous other legal, ethical and professional concerns which may govern the proper use of images.

However, there is a theoretical possibility of a legal argument that to take a photograph of tissue is to 'use' that tissue. So if a photograph is taken for a scheduled purpose (e.g. of internal organs at post-mortem) without Appropriate Consent, it might be argued that, notwithstanding HTA guidance, the Act's provisions had been breached. Consequently, for post mortem tissue, compliance with consent procedures in relation to photography is strongly recommended.

Similarly, manipulating human tissue (e.g. cutting and staining extra sections) specifically in order to take photomicrographs is not covered by the GMC guidance and this may be a Scheduled Purpose, depending on the purpose for which the photomicrographs are being taken.

Are plasma and serum covered by the Act?

No – not if they are properly prepared, because the Act defines tissue as containing cells which have been made by a human body. However, if your preparation method leaves as much as one intact cell in the plasma or serum, a legal argument could be made.

By the same token, saliva, urine, faeces, serous effusions and pus ARE all human tissues and are covered by the Act's requirements for consent and licensing, depending on their origin (from the living or post-mortem) and the purpose of their use.

Will all mortuaries be able to remove and store material for research?

It is the HTA's intention that all post-mortem facilities that apply for a licence and complete the compliance report will actually receive **three** licences.

So all mortuaries will be licensed for:

1. The making of a post mortem examination
2. Storing the body of a deceased person, or 'relevant material' from a human body for use for a Scheduled Purpose
3. Removal from the body of a deceased person material of which the body consists or which it contains for use for a Scheduled Purpose other than post mortem or transplantation.

The relevant 'scheduled purposes' to which these licences refer are:

1. Determining the cause of death
2. Establishing after a person's death the efficacy of any drug or other treatment administered to him.
3. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
4. Public display
5. Research in connection with disorders or the functioning of the human body
6. Clinical audit
7. Education or training relating to human health
8. Performance assessment
9. Public health monitoring
10. Quality assurance.

Consequently we believe that, in practice, all mortuaries will be licensed to remove and store material for research. Of course, you must comply with any specific conditions of the licence.