

HUMAN TISSUE (2004) ACT - GUIDANCE FOR RESEARCHERS

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Introduction

The Human Tissue (2004) Act (HT Act) requires the storage of Human Tissue (HT) to be licenced subject to a few exemptions. The regulatory authority for the HT Act is the [Human Tissue Authority](#) (HTA) who provide all the information required for individuals or organisations that may be working with HT and function as the prosecuting authority.

Other than research, there are many other uses of HT requiring storage e.g. mortuaries, in teaching, organ donation *etc.* Guidance is available from the comprehensive [HTA website](#).

Considerations of the Human Tissue Act (2004) for teaching

Advice from the Human Tissue Authority has confirmed that tissue stored for teaching purposes is exempt from requirements to hold a licence:

Under paragraph 3(2) of the Human Tissue Act 2004 (Ethical Approval, |Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, 'storage' of relevant material from a living person is exempt from licensing where the person storing it is intending to use it for any purpose specified in paragraphs 2-5 or 8-12 of Part 1 to Schedule 1 to the Act.

HOWEVER IT IS THE RESPONSIBILITY OF THOSE PLANNING TEACHING TO CONSULT THE ACT AND RELEVANT GUIDANCE TO ENSURE THEY REMAIN WITHIN THE LAW

Considerations of the Human Tissue Act (2004) for researchers

Investigators who intend collecting any human tissue or fluids for research should read the [List of materials considered to be 'relevant material' under the Human Tissue Act 2004](#) and then the [Code of Practice for Research](#) (HTA Code 9³), for current guidance.

IT IS THE RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR TO ENSURE THAT THEIR RESEARCH IS LEGAL AND MAKE AN APPLICATION TO THE HEALTH RESEARCH AUTHORITY IF RELEVANT MATERIAL IS TO BE USED.

A particular, and common misunderstanding with the HT Act, relates to the unfortunate position that the Act does not define storage. The HTA do not recommend that Institutes re-write the comprehensive guidance already available, and instead directs researchers to the [HTA website](#). However, given the lack of definition of storage, a number of examples taken from the HTA code of practice E are reproduced below.

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³ This becomes "Code E" from April 2017.

If UoP researchers are unclear what they need to do to ensure that they are in compliance with the HT Act from reading the HTA guidance, and from working through the examples below, they can either:

- a. Submit their proposal for ethical review through the Health Research Authority (HRA), where the "[No material ethical issues tool](#)" will help researchers to decide whether their study is appropriate for Proportionate Review (response within 14 days) or standard review (60 days).
- b. Seek advice from the University Ethics Advisor (Dr Simon Kolstoe) who may assist with an enquiry to the HTA on whether the research proposal / protocol requires HRA review (*in lieu* of a Human Tissue Licence), or whether the proposed research does not represent storage of HT and is therefore exempt from the HT Act, or meets one of the following exemptions:
 - i. The HT is being stored for no longer than 7 days prior to being rendered acellular for storage and subsequently used in research after that (*but see examples below*).
 - ii. The HT is being stored for no longer than 7 days prior to being transported to a facility licenced to store such HT.

Examples of HT use for Investigators sampling tissue directly from volunteers

All the following examples assume that they are part of a study for which a favourable ethical opinion has been received from a Faculty Ethics Committee, and the volunteers from which the samples are collected have given their informed consent for the tissue to be collected and tested in accordance with the study protocol which has received the favourable ethical opinion.

The following advice is reproduced from:

<https://www.hta.gov.uk/sites/default/files/files/Code%20E.pdf>

84. A licence to store relevant material for research within the scope of the HT Act is not required in the following circumstances:

a) It is from a person who died prior to 1st September 2006 and at least one hundred years have elapsed since their death.

This exemption from licensing is set out in the HT Act.

b) It is being held 'incidental to transportation'.

This exemption from licensing is set out in the HT Act. This term is not defined in the law and the HTA has interpreted this as the temporary holding of material in transit, while it is being conveyed from one place to another. We consider the timeframe for this to be a matter of hours or days and no longer than a week. The intention of the wording of that interpretation is not to designate a seven-day exemption period, but rather to indicate that the material should be held for as short a period as possible. The focus is on hours or days, rather than one week.

Example

Skin biopsies for use in research are collected across a number of sites and batched before being sent to an establishment licensed by HTA for storage for research. The multiple sites collecting the biopsies do not need to be licensed as the storage is pending transportation to a licensed establishment.

c) It is being held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular).

The HTA views this as analogous to the incidental to transportation exception above. The HTA therefore takes the position that a licence is not required in these circumstances, providing the processing takes a matter of hours or days and no longer than a week. In summary, if there is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells, then no storage licence is required

Example

A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not relevant material, the blood does not need to be stored under a HTA licence.

d) Further examples where a HTA storage licence would not be required:

Example 1

A whole blood sample is taken and this is then immediately sampled for blood lactate levels in the plasma, then the sample is disposed of about five minutes following the sample being taken.

Conclusion: No storage of relevant material for research would be taking place.

Example 2

A whole blood sample is taken and this is then immediately processed for various tests that day, some of which includes testing directly on the cells themselves. All samples are disposed of when the tests are complete, later that day.

Conclusion: No storage of relevant material for research would be taking place.

Example 3

A whole blood sample is taken and made acellular immediately, and only serum is retained for research.

Conclusion: No storage of relevant material for research would be taking place.

Example 4

An experiment is conducted over a 6 day period. Whole blood samples are provided by volunteers throughout the sample collection period. All the samples are made acellular by day 7, with only serum being stored for research.

Conclusion: There is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary (a few days) and for the purpose of obtaining research material which does not contain cells. The serum is the material which will be stored for research, and this does not require a HTA licence.

Example 5

A study has received approval from a recognised REC where blood samples are taken during a clinical trial.

Conclusion: No HTA licence is required to store samples for which REC approval has been obtained (see paragraph 86).

e) Example where a HTA storage licence would be required:

Blood samples from healthy volunteers are collected from two groups of participants as part of a research study over a two-day period. After each collection, the samples are stored in a refrigerator and then analysed for research, as a batch, once all have been collected. All samples are used and disposed of within seven days of the first collection. The project involves healthy volunteers and has not been approved by a recognised REC.

Conclusion: Although the storage period is for only 2-3 days, relevant material samples (whole blood) are being stored solely for the purpose of research within the scope of the Act; a HTA storage licence is therefore required.

Please note that even if the research destroys the cells, this does not alter the point that prior licensable storage of relevant material for research would have taken place.