

### [Does all research with human tissue need a licence under the HT Act?](#)

No. Importantly, an HTA licence is for the storage for use in research, not the use itself. Specific research projects undertaken with approval from recognised Research Ethics Committee (REC) committees (or for which approval by such a committee is pending), do not require an HTA storage licence. (This is discussed further below in the question “Do I need a licence to store tissue or cells for a specific research project if it has ethical approval?”) In addition, researchers storing tissue samples received from a REC-approved tissue bank do not require a HTA storage licence. Finally, storage that is incidental to transportation or with the intent to render material acellular does not require an HTA licence. More information on the requirements for consent and ethical approval is included in flowcharts within the [code of practice on Research](#).

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

### [Do I need a licence to store tissue or cells for a specific research project if it has ethical approval?](#)

No. An HTA licence is not needed for storage of tissue for certain ethically approved research or a specific research project for which ethical approval is pending from a recognised Research Ethics Committee (REC), which is either:

- a REC established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, or
- an ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

The HTA and National Research Ethics Service (NRES) have agreed a position whereby NHS RECs can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. This approval can extend to specific projects receiving non-identifiable tissue from the bank. The tissue does not then need to be stored on HTA-licensed premises; nor does it need project specific ethical approval.

However, a licence is required for material stored (e.g. in large biobanks) for which there is no ethical approval.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

### [Can consent from a patient be generic and enduring?](#)

Yes, consent can be generic and enduring. The HT Act sets the baseline that, for lawful storage and use of tissue for Scheduled Purposes, consent must be obtained from the appropriate person. The scope of that consent is not limited by the HT Act. Guidance for obtaining consent is provided in the HTA's codes of practice and other documents. It can be whatever is agreed in different circumstances.

Anticipating and explaining the purpose for which tissue could be used will avoid the need for seeking repeated consents – for example for research after the patient has had surgery or giving tissue which may be stored for use in a future, unspecified, project

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### [Do I need a licence to store tissue from living people?](#)

An HTA licence is not required if human tissue is stored for a specific research project which has ethics committee approval from a recognised Research Ethics Committee (REC), which is either:

- a REC established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, or
- an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004, (further details are given in the code of practice on Research at.) or is pending such approval.

If researchers wish to retain tissue for future, unspecified, research after the expiry of project-specific ethical approval, then a licence under the HT Act will be required. Application for a licence should be made in good time: we recommend at least three months before the ethical approval ends.

Alternatively, an application for ethical approval for the new specific research project should be made in good time to preempt the expiry of the project-specific ethical approval. The samples will need to be transferred to existing, licensed premises until either a licence is granted or new, appropriate ethical approval has been obtained.

Most research institutions and NHS establishments have a licence from the HTA so researchers should be able to transfer human tissue to licensed premises for storage in their own organisation, subject to the agreement of the Designated Individual for the licence.

Human tissue is a valuable resource for research, and disposal should always be a last resort.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

#### [Is patient consent needed even to use a tiny bit of residual material for research?](#)

'Residual' blood or tissue from the living can be used without consent only if the research is ethically approved by a recognised Research Ethics Committee (REC; see above and the [code of practice on Research](#)) and the researcher cannot link the blood or tissue to the patient. Consent is needed for any of the HT Act's Scheduled Purposes where the tissue is from a deceased person.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

#### [Are cell lines defined as relevant material?](#)

Primary human tissue and cells i.e tissues and cells removed directly from a person are defined as relevant material under the HT Act. Cell lines resulting from expansion of primary cell cultures are not relevant material, as all the original cells have divided and so have been created outside the human body. The storage of cell lines for research does not require an HTA licence.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

#### [I am a researcher. I've heard that I do not require a HTA licence to store tissue for my research project if I obtain my tissue from a research tissue bank. Is this true?](#)

The HTA and National Research Ethics Service (NRES) have agreed a position whereby NHS Research Ethics Committees (RECs) can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises. This approval can extend to specific projects receiving non-identifiable tissue from the bank. The tissue does not then need to be stored on HTA-licensed premises; nor does it need project specific ethical approval.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>

#### [Is valuable research similar to that undertaken before the HT Act now impossible without patients' consent, for example the discovery of the link between Helicobacter pylori bacteria and stomach ulcers coming from examination of archived ulcer samples?](#)

No. Research can take place without patients' consent if the tissue has been anonymised and the project has been approved by a recognised Research Ethics Committee (REC) which is either:

- a REC established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, or
- an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004, (further details are given in the code of practice on Research at.) or is pending such approval.

Use of existing tissue holdings (material from the living or deceased that was already held at the time the HT Act come into force on 1 September 2006) does not need legally require consent. However, if practical, the consent of the participant should be sought and the views of the deceased person or of their family (if known) must be respected. In addition, the potential benefits of the research should outweigh any potential harm to donors of the samples. Further details are given in the [code of practice on Research](#). Of interest, although the work on Helicobacter pylori and stomach ulcers was often cited as an example of what could be lost to UK science as a result of the HT Act, this groundbreaking research into the cause of such ulcers actually took place in Australia.

- See more at: <https://www.hta.gov.uk/faqs/research-faqs#sthash.jePD4OPY.dpuf>