Research & Enterprise Services | Lancaster University

Human Tissue Act – Guidance for Lancaster University Researchers

1. Summary

A Human Tissue Authority (HTA) licence is needed for the *storage* of material for use in unspecified research. Lancaster University does not hold a HTA licence. Any research at Lancaster involving human tissue which will be kept for the duration of the project must be approved by the NHS Research Ethics Committee (NHS REC). Tissue cannot be stored for future unspecified projects.

2. Material covered by the HTA

The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material. Follow this link to a full list of relevant materials

3. Licence exemption-requirements

- Specific research projects undertaken with approval from the NHS REC, or for which approval is pending, do not require an HTA licence. The human tissue can only be kept for the length of time specified in the project's NHSREC ethical approval.
- Storage that is incidental to transportation or with the intent to render material acellular does not require an HTA licence.
- Tissue must not be retained for future, unspecified, research after the expiry of project-specific NHS REC ethical approval. However, an application for ethical approval for a new specific research project using the same tissue can be made to the NHS REC. This should be done in good time to pre-empt the expiry of the original project-specific ethical approval. When applying for an extension to an existing ethical approval, please copy ethics@lancaster.ac.uk into all correspondence
- If new approval has not been sought or obtained before the end date of the original ethical approval the samples would need to be transferred to licensed premises until new NHS REC approval has been obtained.
- More information on the requirements for consent and ethical approval is included in flowcharts within the HTA code of practice on research.

4. Generic ethical approval for tissue banks

As of 30 October 2006, licensed tissue banks are able to apply for generic ethical approval for research using tissue that they supply. This means that straightforward projects can be carried out using tissue supplied by an ethically approved tissue bank without the need for ethical approval from an NHS REC for the individual project. Before providing samples these tissue banks will expect to see approval from the appropriate Faculty Research Ethics Committee.

5. Sample storage/destruction

Samples must be returned to the appropriate tissue bank or destroyed once the project has been completed.

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

A list of FAQs relating to the Human Tissue Act and research can be found here:
https://www.hta.gov.uk/faqs/research-faqs