

## Research on human tissue – regulatory requirements and good practice

**The Human Tissue Act 2004** (the Act) and subsequent regulations set the regulatory parameters of research on human tissue. The Legislation encompasses the European Directive **2004/23/EC** on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The **Human Tissue Authority** (HTA) oversees all regulatory affairs relating to human tissue.

Under the Act, human tissue is defined as material that has come from a human body and consists of, or includes, human cells.

The Act does *not* apply to research on cells or cell lines which have been derived from human tissue after they have been cultured in vitro – but it does apply to the tissue from which the cells were derived from.

The Act sets out which activities involving human tissue can only be conducted if licensed by the HTA.

### Research does *not* require a license by the HTA if all of the following conditions are met:

- 1) The research is approved by a recognised ethics committee (usually this must be an ethics committee within the official NHS framework) or such approval is pending; **and**
- 2) The researchers are not likely to come into possession of information from which the person from whose body the material has come can be identified. (The tissue does not need to be 'absolutely' anonymous – e.g. a treating clinician who is not involved in the research may still be able to link the tissue back to a patient); **and**
- 3) The tissue is destroyed after the ethics committee approval expires (i.e. the tissue may not be 'banked' for prospective future use, unless ethics approval is already in place for that use) .

If those conditions do not apply, research can only be conducted under a HTA license.

The HTA sets certain standards for handling human tissue – it is good practice to work towards meeting these standards, whether or not the research is licensable.

As part of **good practice** the following considerations apply:

**People:** All personnel handling human tissue are aware of the requirements of the Act. Training is provided at induction and on an on-going basis. Meetings are held to coordinate practices and new developments are disseminated to all relevant personnel. The 'designated individual' in the license must be in a position to oversee and direct all activities under the license. Appropriate 'persons designated' assist in this process.

**Policies:** All aspects of the licensable work are supported by ratified documented policies and procedures which are written by the appropriate people and reflect working practices. There is a systematic and planned approach to the management of files that record the use or disposal of samples.

A coding and records system facilitates traceability and alerts researchers to when tissue needs to be disposed of either for biological reasons or because ethical approval is expiring. There are systems to ensure that all adverse events, risks and complaints are investigated.

**Facilities:** The premises are fit for purpose. Environmental controls are in place to avoid potential contamination. Security controls protect tissue and records. Adequate systems protect the quality and integrity of tissues and cells during transport and delivery. Records of equipment maintenance are recorded and duplicate pieces of equipment (i.e. storage freezers) can be used as a contingency.

Crucially, **consent** must be obtained in accordance with the requirements of the HT Act 2004 and as set out in the HTA Code of Practice. Under HTA guidance it is legitimate for a researcher to take consent of his/her own patients and consent can be generic and enduring.

Please note that if you culture tissue specifically for clinical therapeutic use another, more stringent set of regulatory requirements applies

The above is a very brief introductory overview.

For further information, guidance and training please

- visit the HTA website: <http://www.hta.gov.uk> or
- contact Sebastian Sethe at [legal@nesci.ac.uk](mailto:legal@nesci.ac.uk)