

## **RESEARCH INVOLVING HUMAN TISSUE**

In the United Kingdom, the use of human tissue or primary cells for research purposes is legally regulated; primarily by the Human Tissue Act 2004 (HTA). The Act makes it a criminal offence to engage in various activities involving human tissue and cells, such as storage without a licence (issued by the Human Tissue Authority) or using human tissue or cells outside a research project that has been authorized and approved by a 'recognised ethics review committee' (RERC).

University research ethics committees are not 'recognised' committees for this purpose and researchers will therefore have to seek approval from a RERC prior to commencing research in order to ensure that the research complies with all the ethical and legal requirements. Currently, RERCs are all Research Ethics Committees under the auspices of the National Research Ethics Service (NRES) within the National Research Ethics Service (NRES) for England or within the wider UK Health Departments' (UKHDs) Research Ethics Service, together with all ethics committees recognised by the United Kingdom Ethics Committee Authority (UKECA) under the Medicines for Human Use (Clinical Trials) Regulations 2004.

The types of human tissue and cells that are covered by the HTA are referred to as 'relevant material'. The relevant materials covered by the HTA include materials that have come from a human body, whether living or dead, including body parts, organs and human cells. Established cell lines are not relevant material, but primary cell cultures are. Storage of established cell lines for research does not require a licence, nor does research using cell lines require ethical review (except in the case of human embryonic stem cell lines – see next paragraph).

The storage and use of human reproductive cells and embryos outside the body is regulated separately, by the Human Fertilization and Embryology Authority (HFEA), under the Human Fertilization and Embryology Act (2008). All research involving human reproductive tissue requires a research licence from the HFEA and must undergo ethical review. The use of stem cell lines, derived from human embryos (human embryonic stem cells), in research requires approval from the MRC UK Stem Cell Bank Steering Committee to ensure that research performed is in keeping with HFEA Regulation. The process of obtaining approval does require institute signature which states they will abide by the "Code of Practice for the Use of Human Stem Cell Lines".

The HTA does not cover hair and nails from a living person. However, the HTA makes it a criminal offence to hold human tissue - including hair, nail, and gametes (i.e. cells connected with sexual reproduction) – for the purpose of DNA analysis, without the consent of the person from whom the tissue or cells came (or of those close to them if they are deceased). Medical diagnosis and treatment and criminal investigations are excluded.

It is important to distinguish between the *licensing* by the Human Tissue Authority of premises as approved storage facilities for human tissue - for further details of which consult the Specialist Research Ethics Guidance Paper, 'Human tissue research' - and the *ethics approval* of research involving human tissue.

Ethics approval by a RERC for human tissue research is a legal requirement under the HTA in the following circumstances:

- if a specific research project involves the storage or use of relevant material on premises without a licence from the Human Tissue Authority to store relevant material for scheduled purposes;
- if the research involves the storage or use of relevant material taken from a living person without their consent for the research (in which case, in addition to ethics approval, the research must be conducted such that the donors are not identifiable to the researchers); or
- if the research involves the storage or use of bodily material from a living person with the intention of undertaking DNA analysis without consent for such analysis (in which case, in addition to ethics approval, the research must be conducted such that the donors are not identifiable to the researchers).

Relevant material – human tissue or cells – can be obtained for research purposes in two ways:

First, it can be obtained from a human tissue bank that is licensed by the Human Tissue Authority to house tissue for unspecified research. The research purpose(s) must, however, be specified prior to the use of the tissue or cells, and must comply with the human tissue bank's conditions, which will include:

- evidence of independent scientific approval;
- compliance with the terms of the donor's consent;
- anonymisation of the relevant material at the point of release; and
- compliance with a supply agreement.

Second, it can be obtained by application to a RERC for ethics approval for a specific research project that will include the collection of human tissue or cells. At the end of a research project the relevant material must be handled in one of the following three ways: deposited in a human tissue bank licensed by the Human Tissue Authority; used for a new research project (after new RERC ethics approval); or destroyed.

The regulatory framework on human tissue and cells is in a state of development, with continuing revisions and updates of the guidance by regulators to ensure that the regulations keep abreast of fast-moving technology. If a researcher is in any doubt as to whether her/his research project requires ethical approval from any of the above bodies, or the University's Ethics Review Procedure s/he must seek guidance from UREC.

For further information and discussion, see the Specialist Research Ethics Guidance Paper, 'Human tissue research'.