Specialist Research Ethics Guidance Paper

RESEARCH INVOLVING HUMAN TISSUE

This guidance paper should be read in conjunction with the University’s Research Ethics Policy Note no. 11 (Research involving human tissue), which is part of the University’s Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue.

1. Definition of human tissue

Human tissue is defined by the Human Tissue Act 2004 (HTA Act) as relevant material (the HTA website: www.hta.gov.uk). The relevant materials covered by the HTA Act include materials that have come from a human body, whether living or dead, including body parts, organs and human cells. Cell lines are not relevant material under the Act (although primary cell cultures are). Cell lines which are intended for human application (i.e. for clinical uses or treatment) are considered relevant material under the European Union Tissue and Cells Directive (Directive 2004/23/EC). Storage of cell lines for research-only purposes does not require a licence; storage of cell lines for potential human application does. The HTA Act does not cover hair and nails from a living person. However, the HTA Act makes it a criminal offence to hold relevant material – including hair, nail, and gametes (i.e. cells connected with sexual reproduction) – for the purpose of DNA analysis, without the informed consent of the person from whom the relevant material came (or of those close to them if they are deceased).

The HTA's list providing supplementary guidance on relevant material: https://www.hta.gov.uk/sites/default/files/Supplementary_list_of_materials_200811252407.pdf

HTA guidance on stem cells and cord blood: www.hta.gov.uk/licensingandinspections/sectorspecificinformation/stemcellsandcordblood.cfm

2. Regulations, licensing, ethics approval and consent

The HTA Code of Practice 9 for Research includes:

- a flow diagram that summarises the licensing and consent requirements for relevant material for research from the living – Appendix A
- a flow diagram that explains the link between ethical approval and the licensing and consent exceptions – Appendix B.

The HTA Code of Practice 9 for Research: www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm

2.1 Regulations

The HTA Act makes it a criminal offence to engage in various activities involving relevant material, such as storage of tissue without a licence (issued by the HTA).

Where the research involves relevant material intended for human application (i.e. for clinical uses or treatment) the research must be conducted in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Where such research is subject to the Clinical Trials Regulations it will require clinical trial authorisation from the Medicines and Healthcare Products Regulatory Authority (MHRA) and ethical approval from a United Kingdom Ethics Committee Authority (UKECA) – RREC. If the research is not subject to the Clinical Trials Regulations it will require ethical review by a REC within the UK Health Research Authority if it is conducted in or through the NHS.

2.2 HTA licensing of premises as approved storage facilities for relevant material
If storing relevant material for the purpose of research a licence under the HTA Act is required. If storing relevant material for the purpose of potential human application a licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 is required.

If storing relevant material from the deceased a licence is required, unless it is more than 100 years old or it is for a specific research project that has ethics approval from a RERC (or ethics approval is pending) or storage is incidental to transportation (for less than 1 week).

If storing relevant material from the living a licence is required, unless it is for a specific research project that has ethics approval from a RERC (or ethics approval is pending), storage is incidental to transportation (as above) or it is stored with intent to render acellular (for less than 1 week).

2.3 Legal requirement for ethics approval
Ethics approval by a Recognised Ethics Review Committee (RERC) for relevant material 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 HTA 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);
- 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); or
- if relevant material (for example, blood) is collected or removed from healthy volunteers, rather than being already stored within a licensed tissue bank. This is the case even if the relevant material is destroyed within a short period of time (an exemption from the Human Tissue Act 2004’s licencing requirements may apply if it is storage incidental to transportation).

Ethics approval is required in order to obtain an exemption from the Human Tissue Act 2004’s licencing requirements for the storage of relevant material and/or is required in order to obtain consent in the case of living donors.

2.4 Legal requirement for consent
If the research is storing relevant material from the deceased then, unless the relevant material has been obtained before 1 September 2006, consent is always required.

If the research is storing relevant material from the living then consent is required, unless the relevant material has been obtained before 1 September 2006 or it is non-identifiable to the researcher and is for a specific research project that has ethics approval from a RERC.

In the case of new relevant material from the living it is good practice to obtain prospective consent to use the relevant material in research where this is practicable.

3. Ethics approval by the University but not by a Recognised Ethics Review Committee (RERC)
In the context of this guidance paper on research involving human tissue, the University’s ethics review procedure applies in the following cases:
- Using blood of normal volume a research project, which is taking place on NHS premises and/or involving NHS staff, is analysing white blood cells immediately and then destroying them (i.e. no storage);
- Using blood of normal volume a research project is spinning down cells, taking plasma and cerium and discarding red/white cells and then storing.

If cells do not divide and are only being used for an experiment then they are not covered by the HTA.