

Human Tissue Act 2004 and the role of Research Ethics Committees (RECs)

The Human Tissue Act 2004 (“HTA”) sets up two requirements for the conduct of research on “relevant material”:¹ consent for storage and use, and licensing for storage.

Consent is dealt with in section 1: various activities including storage of and research on relevant material require the consent of the person whose body it derives from. There is an exemption in section 1(7) for material taken from a living person provided that (s 1(9)) the sample is anonymised to the researcher (i.e. keyed anonymity is acceptable) and the research is ethically approved in accordance with regulations to be made under the Act.

The regulations made under this provision are the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 SI 2006 No. 1260 (“the Exceptions Regs”)² These regulations set out the types of Research Ethics Committees (“RECs”) that can give the ethical approval required to confer exemption from the Act’s consent requirement; NHS RECs are among these, but University RECs are not.³

There is an exemption from the consent requirements for existing holdings, in section 9 of the HTA; again, this depends upon the holdings having been the subject of approval by a REC of the kind specified in the Exceptions Regs

Licensing is the subject of section 16. A licence must be obtained from the Human Tissue Authority for, among other things, the storage of “relevant material which has come from a human body” for any of the purposes listed within Schedule 1. These include “research in connection with disorders, or the functioning, of the human body”. There is no exemption for existing holdings.

¹ Defined section 53 “material, other than gametes, which consists of or includes human cells”. Obviously this includes blood. Whether or not it is intended to include urine and faeces is a moot point but most people consider that it does not.

² <http://www.opsi.gov.uk/si/si2006/20061260.htm>

³ The Exceptions Regs defines a REC that can give approval for the purpose of the exempting provisions of the HTA as

- “(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, or
- (b) any other committee established or person appointed—

- (i) to advise on, or on matters which include, the ethics of research investigations on relevant material which has come from a human body, and
- (ii) recognised for that purpose by, or on behalf of, the—

- (aa) Secretary of State,
- (bb) National Assembly for Wales, or
- (cc) Department of Health, Social Services and Public Safety”

However, the Exceptions Regs exempts from the licence requirement research which has been approved by a REC. Again, the REC must be of a kind approved under the Exceptions Regs.

The University does not hold a general licence under the Act, but a licence is held by the Department of Food and Nutritional Sciences.

The storage or use of material in contravention of the consent requirement or the licence requirement is a criminal offence.

Consequences for the storage and use of relevant materials at this University

(a) Existing holdings:

Most of these will comply with the consent requirement because most should have been obtained subject to the requirements of this Committee.

However, all the University's existing holdings are held in breach of the HTA's licensing requirement unless they were obtained pursuant to approval by an NHS REC

(b) New research:

Where a researcher wishes to obtain and use relevant material from 1st September 2006 onwards, although this Committee's requirements will ensure that the HTA's consent requirements are met, the University can only at present meet the licensing requirement in relation to research that is conducted in the Department of Food and Nutritional Sciences. Other research must, accordingly, be approved by an NHS REC. Research that is conducted by the Department of Food and Nutritional Sciences that is covered by the terms of the HTA License held by that Department will not have to be approved via any NHS REC for this purpose. Projects in other Schools that are in collaboration with the Department of Food and Nutritional Sciences (that is, a researcher from Food and Nutritional Sciences is a co-investigator on the project) will be covered under the licence providing the research meets the terms and conditions of the licence. Such research must be approved by the University REC and not dealt with by the school itself.