Human Tissue Act compliance

The Human Tissue Act 2004 repealed and replaced the Human Tissue Act 1961 (in England and Wales). The Act makes it unlawful to remove, store or use human tissue from the living or deceased without consent to do so for specified health-related purposes or public display, and is punishable by a fine and/or 3 years' imprisonment. In addition, there are a number of activities in the Act that require a license from the Human Tissue Authority before they can be lawfully undertaken.

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes (such as research, transplantation, and education and training) set out in the Human Tissue Act. In order to carry out research that leads to human benefit, Royal Holloway and New Bedford College uses and stores tissue that falls within the remit of the HTA. The College therefore has obligations under the Human Tissue Act.

The definition of relevant material in the Human Tissue Act 2004 (excluding human application) is:

Section 53: Relevant Material:
1. In this Act, “relevant material” means material, other than gametes, which consists of or includes human cells.
2. In this Act, references to relevant material from a human body do not include:
   (a) embryos outside the human body, or
   (b) hair and nail from the body of a living person. (Human Tissue Authority)

To supplement the HTA's broader policy framework on relevant material, a list has been produced to provide stakeholders with guidance on whether specific materials fall within the definition of relevant material under the Human Tissue Act. Please see the supplementary list of materials for the purposes of the Human Tissue Act 2004.

The College has a licence from the HTA to store human tissue samples for research purposes. However, you are still required to seek ethical approval for each project via the NHS HRA (Health Research Authority) REC (Research Ethics Committee) and to keep the College Ethics Committee informed as this progresses by seeking College approval in parallel. An HTA licence on its own does not permit the 'use of tissue for research or approve an individual research project or clinical trial'.

Not all human tissue requires a licence. If the tissue comes from living people and there is project specific approval from a recognised REC, then you are allowed to store the material for the duration of that specific project. Material (tissue or primary cells) not used must be appropriately destroyed at the end of the project.

In either case, seek guidance from the Designated Individual (College employee responsible for oversight of compliance with the terms of the licence, BSO@rhul.ac.uk)

Further guidance

- HTA legislation
- HTA guiding principles
- Post-mortem examinations
- Research
- Human Tissue Act 2004