

## Factsheet on research within the scope of the Human Tissue Act 2004 – June 2011

The Human Tissue Act 2004 (the Act) contains a number of provisions to facilitate *Research in connection with disorders, or the functioning of, the human body*. Working within the requirements of the Act, the HTA's approach to regulating research aims to support researchers. This factsheet summarises the key requirements for human tissue research under the Act. It is not intended to replace or supersede the detailed information that the HTA already provides on its [website](#).

The information in this factsheet is accurate at the time of publication (27 June 2011). You can keep up-to-date with regulatory requirements by visiting our website and researchers are encouraged to read the [HTA's codes of practice](#), [frequently asked questions](#) (FAQs) and [subscribe to the HTA's e-newsletter](#).

### 1. Relevant material

The material that the Act covers is called 'relevant material', which is material that consists of or includes human cells.

'Relevant material' includes blood, tissues and organs. It does not include:

- Material which contains no cells e.g. serum.
- Gametes (ova and sperm).
- Material created outside of the body e.g. embryos, cell lines.

More information about relevant material can be found on the [HTA website](#).

For the purpose of DNA analysis, the Act makes reference to 'bodily material' and more information can be found on the [HTA website](#).

### 2. Consent

Under the Act, consent is broadly required to store and use relevant material from the living for a number of 'scheduled purposes', including 'research in connection with disorders, or the functioning of, the human body'. Consent is also required to remove, store and use relevant material from a deceased person.

This consent must be both appropriate and valid.

*Appropriate consent* means that it must come either from the donor themselves, if they are alive, or from the person highest up the Act's qualifying relationship

hierarchy, if they are dead. The hierarchy is set out in section 27(4) of the Act and can be found in the [HTA's code of practice on Consent \(paragraph 83\)](#).

*Valid consent* means that the person must have the capacity to consent, be appropriately informed, and give consent freely.

In the case of research on material for transplantation within the scope of the Act, it is the consent of the donor, or the highest ranking person in a qualifying relationship, which is required for any research conducted prior to the organ or tissue being implanted in to the recipient.

### *Consent exceptions*

Under the Act, consent is **not** required to store and use relevant material for research in the following circumstances:

1. The material has been obtained before 1 September 2006.
2. The material is from a living person **and** the proposed research project has been approved by a recognised research ethics committee (e.g. an NHS REC) **and** the material is not identifiable to the researcher.

For more information on all the Act's consent exceptions, please refer to paragraphs 37-54 of the [HTA's code of practice on Research](#).

### **3. Licensing**

The Act requires a range of separate activities to be licensed by the HTA. Unlike other research bodies, the HTA does not approve individual projects or license the research activity itself.

The HTA is required to license the following activities relevant to research:

- Removal of relevant material from the deceased for the scheduled purpose of research.
- Storage of relevant material (from both the living and the deceased) for the scheduled purpose of research.

Without exception, removal of relevant material from the deceased for research within the scope of the Act must take place on premises licensed for this activity. This means that if a person wishes to remove relevant material from a deceased organ donor, for the scheduled purpose of 'research in connection with disorders, or

the functioning of, the human body', the removal must always take place on premises licensed by the HTA for that purpose.

The majority of our post mortem establishments hold this type of removal licence within their suite of HTA licences. Therefore it is possible to extend an existing licence in an NHS Trust to cover areas outside the mortuary, such as operating theatres. If you feel this might be an option worth considering when planning a research study, please contact us for advice.

### *Licensing exceptions*

As stated above, there are no exceptions to the licensing requirement for the removal of relevant material from the deceased for the scheduled purpose of research.

A licence is **not** required to store relevant material for research in the following circumstances:

1. The material is being held for a specific research project approved by a recognised research ethics committee (e.g. an NHS REC) or where that approval is pending.
2. The material is being stored pending transfer elsewhere, providing it is held for a matter of hours or days, and not longer than a week.
3. The material is being held while it is processed with the intention to extract components that are not relevant material i.e. the material is being rendered acellular. The HTA considers this situation to be analogous the second exception set out above, providing the processing takes a matter of hours or days, and not longer than one week.

For more information on all the Act's licensing exceptions, please refer to paragraphs 55-72 of the [HTA's code of practice on Research](#).