HTA Guidance for toxicologists

The Human Tissue Act 2004

The Human Tissue Act 2004 ('the HT Act') provides a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased, for specific purposes set out in Schedule One of the HT Act ('scheduled purposes'). It makes consent the fundamental principle underpinning these activities and established the Human Tissue Authority (HTA). The HT Act covers England, Wales and Northern Ireland. Separate legislation exists in Scotland [The Human Tissue (Scotland) Act 2006].

The scheduled purposes under the HT Act are as follows:

Purposes requiring consent: general

- Anatomical examination
- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body
- Transplantation

Purposes requiring consent: deceased persons

- Clinical audit
- Education or training relating to human health
- Performance assessment
- Public health monitoring
- Quality assurance

What samples are covered?

The HT Act refers to 'relevant material', defined as 'material, other than gametes, which consists of or includes human cells'. Relevant material taken from a deceased person for analysis includes tissue samples, bone, blood, urine, stomach contents, hair and nails. DNA is not relevant material, as it does not contain cells. A list of relevant material under the HT Act can be found on our website.

The role of the Human Tissue Authority

Under the HT Act, the HTA licenses premises on which the following activities take place:

- anatomical examination
- post mortem examination
- removal of relevant material from the deceased for use for scheduled purposes
- storage of anatomical specimens
- storage of bodies or relevant material from human bodies for use for a scheduled purpose
- public display of a body or relevant material from the body of a deceased person

The HTA does not licence individuals.

The HTA carries out inspections of licensed establishments to ensure that licence conditions and standards are being met. The HTA Codes of practice explain the HT Act's consent and licensing requirements for establishments in the sectors it licenses. In relation to the post mortem sector, the HTA licenses premises where post mortem examinations take place, where bodies are stored prior to post mortem examination and where tissue samples are stored for analysis. It has no regulatory remit over the activities of coroners, and post mortem examinations and tissue retained 'for purposes of functions of coroners' or under the authority of coroners are exempt from the consent requirements of the HT Act.

Who needs a licence and are toxicologists covered?

The removal of relevant material from the body of a deceased person and its subsequent storage for use for a scheduled purpose can only take place on premises licensed by the HTA. However, there are some exemptions.

(i) Under Section 39, relevant material which is stored for criminal justice purposes is exempt from the licensing provisions of the HT Act. Criminal justice purposes are the prevention or detection of crime or the conduct of a prosecution.

(ii) Under the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006, storage of relevant material from the body of a deceased person is excepted from licensing where it has (a) come from licensed premises, (b) is being stored for analysis for a scheduled purpose other than research and (c) will be returned to licensed premises when the analysis is complete.

This means that storage of relevant material for toxicological analysis by a specialist laboratory does not

require an HTA licence if the above requirements are met, or if the material is disposed of during or after analysis. This exemption should not be taken as an authorisation for the long term storage of relevant material without an HTA licence. Laboratories should endeavour to carry out analyses promptly and to inform the police/Coroner of the results without undue delay.

Note that removal of relevant material from a deceased person for criminal justice purposes, or under the authority of a Coroner, does not require consent. However, once police or coronial authority ends, valid consent from a person in a qualifying relationship with the deceased is needed to store or use relevant material for use for a scheduled purpose.

Distinction between police and coroners samples.

The police have the power to seize relevant material as evidence, including material which is held under the authority of the Coroner. When the police have completed their investigations, relevant material that was seized for criminal justice purposes may come under the authority of the Coroner. The use of two different systems for the retention of relevant material can lead to confusion. In particular, it can be very distressing for families to find out that samples were kept without their knowledge by the police. One solution is for all relevant material to be held under police powers and for the police FLO to liaise with families. However, this is a matter to be agreed between the police and the Coroner. Further information is available from the Forensic Science Regulator.

What document trail is expected?

The Forensic Science Regulator and the HTA recommend that the pathologist creates a single list detailing all samples retained at post mortem examination and under whose authority each was retained. The list should be provided to both the police and the Coroner. A record of traceability of each item should be maintained, showing if relevant material has been returned to the body or to the family, or sent elsewhere for further investigation, for example a toxicology laboratory.

Specialist laboratories should keep detailed records of the samples received from, and returned to, licensed establishments, or disposed of, to maintain traceability. Laboratories may wish to periodically audit relevant material in their possession and confirm with the pathologist/licensed establishment whether police or coronial authority is ongoing, or if further analysis is required. This will help to prevent relevant material being retained unnecessarily, and without consent.

Whose responsibility is it to return samples to the family?

There should be systems in place to ensure the specialist laboratory is made aware if the family has requested that relevant material be returned to them, in order that the material can be sent back to the licensed establishment for the family's wishes to be acted upon.

Obtaining consent for storage and use of relevant material for research

Once coronial authority has ended, storage of relevant material from a deceased person for a scheduled purpose requires the consent of: **the person concerned,** or their **nominated representative** (the HT Act sets out the terms for valid appointment of a nominated representative) **or**, in the absence of either of the above; a person in a **qualifying relationship** with the deceased.

Consent must be obtained from the person ranked highest in the hierarchy and is only needed from one person in the hierarchy. The hierarchy of qualifying relationships follows this descending order:

a) spouse or partner (including civil or same sex partner)
b) parent or child
c) brother or sister
d) grandparent or grandchild
e) niece or nephew
f) stepfather or stepmother
g) half-brother or half-sister
h) friend of long standing

This person may be different from the ‘properly interested person’ whom the Coroner notifies that relevant material has been retained, and to whom the options for dealing with it on expiry of the retention period must be communicated. The Designated Individual of the establishment where the relevant material is stored needs to be assured there is appropriate consent for storage for a scheduled purpose.

How should samples be disposed of?

Disposal of relevant material does not need to take place at HTA-licensed premises. By agreement with the licensed establishment, relevant material may be disposed of by the laboratory where it was analysed. Such an arrangement should be documented in a written agreement. Records of disposal (date, reason and method) should be maintained to ensure traceability. Further information about disposal of relevant material can be found in our Code of practice on Disposal of human tissue.

Premises where relevant material is being stored while disposal instructions are being awaited from the Coroner or the police do not require a licence from the HTA.

What should be done with historical samples (pre HTA or potentially those post HTA, which have not been dealt with appropriately)?

Our Code of practice on Disposal provides detailed information on the disposal of relevant material which pre-dates the HT Act (‘existing holdings’). In relation to samples which should have been disposed of, but have not, the HTA can be contacted to provide advice.

Useful documents

HTA Code of practice 1 on Consent

HTA Code of practice 3 on Post mortem examination

HTA Code of practice 5 on Disposal of human tissue

Legal issues in forensic pathology and tissue retention, Forensic Science Regulator

HTA policy on the management and traceability of tissue samples retained by independent pathologists