

Human Tissue Authority Regulatory alert 004/2009

Notice for Designated Individuals regarding compliance reporting and the retention of tissue and organs following post-mortem examination

Issued 8 December 2009 to all licensed establishments in the post mortem sector

Scope

1. This alert is being issued by the Human Tissue Authority (HTA) as the regulatory body in England, Wales and Northern Ireland responsible for implementing the requirements of the Human Tissue Act 2004 (HT Act).
2. It includes information relevant to Designated Individuals (DIs) of all establishments licensed for the making of a post-mortem examination.

Background

3. Site-visit inspections undertaken by the HTA indicate that there is lower than expected compliance with standards relating to consent and governance, including traceability.
4. The practice of storing tissue blocks and slides without appropriate consent under the HT Act continues, despite repeated guidance issued by the HTA, including in our [revised codes of practice](#) on disposal and post-mortem examination.
5. In addition, since April 2008, the HTA has been notified about five incidents which have come to light involving the storage without consent of a brain following release of the body for burial or cremation after a forensic post-mortem (FPM) examination. To preserve the anonymity of those concerned and also out of respect for the bereaved, the main features of these incidents have been compiled into a single fictional case study, as set out below:

Case study

6. A forensic post-mortem (FPM) examination of a middle-aged woman, Mrs A, was carried out at a local NHS Trust mortuary. During the FPM examination a serious head injury prompted the pathologist to retain the brain for specialist neuropathological examination. The coroner was informed and authorised retention of the brain in the knowledge that the full examination might not be completed for several weeks.

The body of Mrs A remained at the local mortuary whilst her brain was transferred to a specialist unit by the police. The family of Mrs A was informed by the coroner's officer that the brain of Mrs A had been sent for specialist examination and they were

asked for their wishes with regard to the future disposal of the brain. The family expressed a wish for the brain to be repatriated with Mrs A's body before its release for the funeral.

The brain of Mrs A was returned to the mortuary by the police after the examination was complete and placed into storage. The pathologist submitted his findings to the coroner, who sent notification to the mortuary that the body of Mrs A could be released for her funeral. Mrs A's body was released to the funeral directors and cremated.

A few months later, a routine audit carried out by staff at the mortuary discovered that the brain of Mrs A had not been repatriated with her body and was still in storage. The Designated Individual contacted the HTA to report the incident.

7. The five incidents caused the bereaved a great deal of distress and difficulties in relation to the return of the organs to them. The incidents happened in different areas of the country and therefore involved different police forces and coronial districts. There is concern that they may be indicative of a wider problem.

8. DIs should be on notice that the HTA will issue General Directions in April 2010 requiring them to undertake an audit of relevant material from the deceased stored on the premises, the results to be submitted to the HTA in writing in September 2010.

9. The HTA is working with the Royal College of Pathologists to define the specification of the audit, which will be issued with the General Directions, helping ensure that it is proportionate whilst giving the HTA the necessary assurances of compliance with the requirements of the HT Act.

10. Additional General Directions will be issued in April 2010 requiring DIs to complete a compliance assessment report against core HTA standards for submission in June 2010.

11. The HTA will seek to assure itself through this audit and compliance assessment report that licensed establishments in the post mortem sector have robust and reliable systems of traceability and records management and that there is knowledge about the nature and quantity of relevant material stored on the premises.

12. The requirements of the compliance assessment report will be issued in April 2010.

13. It is important that DIs understand that they are responsible for ensuring suitable practices take place on licensed premises. This includes ensuring that there are robust systems of traceability and audit, in order that the risk of organs being retained beyond the period required by the coroner, or the police as part of a criminal investigation, is mitigated.

14. HTA site-visit inspections for the remainder of 2009/10 and in 2010/11 will focus on consent, traceability and records management. In addition, DIs will be expected to demonstrate that material stored on the premises is subject to audit and review to ensure that material is not being stored without appropriate consent.

Further guidance

15. The HTA is engaged in a programme of work to address the continued non-compliance in the post mortem sector. This programme of work is supported by organisations including the Department of Health, devolved assembly governments, Ministry of Justice and Home Office.

16. Guidance on compliance with HTA standards can be found on our website. This includes:

a. HTA codes of practice

www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

b. Summary of compliance report 2008/09

www.hta.gov.uk/publications/summarycompliancereports2008-09.cfm

c. Model communication flowchart for coroners' post-mortem examinations

www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm

17. Note that the codes of practice on disposal and post-mortem examination require that if the family of the deceased do not, or cannot, communicate their decision about what they wish to happen to the tissue, they should be advised that tissue will be held for three months by the pathology department from the time the coroner's authority ends, pending notification of their decision. It should be made clear that if no decision is communicated within that time, the tissue will be disposed of.

18. Please contact the HTA regulation directorate on 020 7211 3400, the Head of Regulation for your geographical area

(see:

www.hta.gov.uk/aboutus/ourpeople/executiveteam/regionalheadsofregulation.cfm)

or email licensing.enquiries@hta.gov.uk if you would like any more information about this regulatory alert.