

**Site visit inspection report on performance against HTA quality standards
Hull York Medical School
HTA licensing number 12078**

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

12 and 13 April 2011

Executive Summary

A site visit inspection of the Hull York Medical School (the establishment) was carried out by the Human Tissue Authority on 12 and 13 April 2011.

The establishment was found to meet all HTA quality standards. Additionally, the HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

The establishment demonstrated a considerable amount of good practice, which is detailed in the concluding remarks of this report.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This was the first HTA inspection of the Hull York Medical School (the establishment). Previously, the establishment was inspected by Her Majesty's Inspector for Anatomy under the Anatomy Act 1984, which was superseded by the Human Tissue Act 2004.

The establishment consists of a main (hub) site at the University of Hull and a satellite site at the University of York. Both sites have purpose-built facilities which are less than ten years old. Eighty medical students are accepted each year at each site. The establishment accepted 20 bodies donated for anatomical examination in 2010 and continues to use bodies donated in past years, for which there is consent for continued storage and use.

Bodies and body parts are stored and used for anatomical examination, teaching and education. Body parts are removed from donated bodies by establishment staff in the course of anatomical examination. A small amount of imported fetal material is currently being stored (until September 2011) on behalf of another party, for research. The HTA had previously given the DI detailed advice and guidance in relation to storage of material for this purpose.

As part of the inspection, the following audit trails were carried out for consent and traceability:

- three bodies in storage were checked against details contained in paper and electronic records
- four body parts in storage were checked against details contained in paper and electronic records
- three records in the electronic database were checked against body parts in storage.

No anomalies were found.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included.

No shortfalls against HTA standards were found during the inspection.

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	N/A	<p>If the establishment wishes to begin loaning anatomical specimens (which can be loaned to both licensed and unlicensed premises), the DI is advised to put written agreements in place with the borrowing establishment as set out in the HTA's code of practice on Anatomical examination (paragraphs 55 – 60):</p> <p>http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code4anatomy.cfm</p> <p>The use of the HTA's model loan agreement is encouraged. This is available on the HTA's website:</p> <p>http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/anatomy/informationforanatomyschools/anatomyforms.cfm</p>

Concluding comments

A considerable amount of good practice was observed by the HTA during this site-visit inspection and examples of these include:

- The establishment has a family room for staff to meet with donors' families, for families to spend time with the donor before their body is used and before cremation, and for handing over ashes following cremation. This acknowledges to donors' families the respect for and gratitude for the donation, and provides a private environment for bereaved families to discuss donations. Plans are in place to put up a plaque of remembrance to acknowledge the value of donations.
- The inspection team was advised that staff visited the contracted incineration company because they felt a duty of care to assure themselves that safe and ethical practices were carried out during the disposal of donor material.
- The HTA model consent form is used for documenting discussions with families when a donation is accepted, which includes how the donated material should be handled when it will no longer be used by the establishment, and consent for / objection to the use of images.
- The DI offers and documents refresher training for staff on the HTA Codes of Practice.
- There is a documented and risk assessed standard operating procedure for the temporary absence of the DI.
- External auditors (usually DIs from other establishments) are brought in on a regular basis to conduct audits to check compliance with meeting regulatory requirements
- All paper records (consent, death certificates, death registration and transfer between sites) are scanned and held electronically.
- Transfer records between the hub and satellite sites include confirmation of receipt.
- To ensure the dignity of the deceased, all material is transported between the hub and main sites during hours when staff know that the number of students and other university staff will be minimal.

The staff working under this licence should be commended for their detailed knowledge of the Human Tissue Act 2004, the HTA Codes of Practice, their teamwork, the effort made to safeguard the dignity of the deceased and the sensitivity shown to donors' families.

Report sent to DI for factual accuracy: 27 April 2011

Report returned from DI: No factual accuracy comments received.

Final report issued: 6 May 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<ul style="list-style-type: none">• Consent forms comply with the HTA's Code of Practice• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose• Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Standard operating procedures (SOPs) detail the procedure for providing information on consent• Independent interpreters are available when appropriate• Information is available in suitable formats
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• Standard operating procedures (SOPs) detail the consent process• Evidence of suitable training of staff involved in seeking consent• Records demonstrate up-to-date staff training• Competency is assessed and maintained
Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
<ul style="list-style-type: none">• Policies and procedures are in place, covering all licensable activities• Appropriate risk management systems are in place• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes• Complaints system
GQ2 There is a documented system of quality management and audit
<ul style="list-style-type: none">• A document control system, covering all documented policies and standard operating procedures (SOPs).• Schedule of audits

<ul style="list-style-type: none"> • Change control mechanisms for the implementation of new operational procedures
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p>
<ul style="list-style-type: none"> • Qualifications of staff and training are recorded, records showing attendance at training • Orientation and induction programmes • Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training • Training and reference manuals • Staff appraisal / review records and personal development plans are in place
<p>GQ4 There is a systematic and planned approach to the management of records</p>
<ul style="list-style-type: none"> • Documented procedures for the creation, amendment, retention and destruction of records • Regular audit of record content to check for completeness, legibility and accuracy • Back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)
<p>GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>
<ul style="list-style-type: none"> • There is an identification system which assigns a unique code to each donation and to each of the products associated with it • An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom
<p>GQ6 There are systems to ensure that all adverse events are investigated promptly</p>
<ul style="list-style-type: none"> • Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
<p>GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</p>
<ul style="list-style-type: none"> • Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose
- Policies in place to review and maintain the safety of staff, authorised visitors and students
- Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons
- The premises have sufficient space for procedures to be carried out safely and efficiently
- Policies are in place to ensure that the premises are secure and confidentiality is maintained

PFE 2 Environmental controls are in place to avoid potential contamination

- Appropriate separation of relevant material
- Air classification system and maintenance of air quality, including control and monitoring of environmental conditions
- Documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings
- Critical storage conditions are monitored and recorded
- System to deal with emergencies on 24 hour basis

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transportation
- Records of transportation and delivery
- Records are kept of transfer agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies

- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 3: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.