Site visit inspection report on compliance with HTA minimum 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.**

10-11 June 2015

Summary of inspection findings

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.

Hull York Medical School (the establishment) was found to have met all applicable HTA standards.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licenses against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

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

Hull York Medical School, (the establishment) is licensed under the Human Tissue Act 2004 (the Act). The two main areas of the establishment's activity are the teaching of anatomy and the storage of relevant material for research within the scope of the Act.

The establishment has been licensed by the HTA since March 2010. This was the second HTA inspection of the anatomy hub (at Hull Medical School) and the satellite (at the University of York), which were first inspected in April 2011.

The second satellite site comprises the Daisy Tumour Bank, which is based at Castle Hill Hospital, Hull. This satellite was added to the main licence in March 2015. At the time of the inspection, licensed activities had not commenced at the Daisy Tumour Bank because the required Memorandum of Understanding (MOU) with the Trust, to cover clinical negligence for non-clinically trained staff to seek consent and to access patient and theatre records, was not yet in place. Once operational, the Daisy Tumour Bank will store tissue collected during diagnostic procedures on patients with suspected or proven cancers.

Anatomy

The anatomy hub and satellite both have secure swipe card access for staff and CCTV is used to maintain oversight of access into the departments.

Prior to commencing anatomy classes, students are required to sign rules of conduct and undertake a comprehensive induction programme. This programme ensures the dignity of donors and the safety of students. During the academic year, students are required to sign in for each class.

The establishment has service level agreements (SLAs) with two undertakers. One undertaker is responsible for the transport of prosections to and from the hub and satellite; the second is responsible for the transport of bodies to and from the undertaker and occasionally between the hub and satellite. Robust transport boxes are used for the transport of body parts. A database of transport records are kept by staff at the satellite and the hub.

The establishment also has collections of potted specimens and bones which are used for teaching; these pre-date the Act.

The anatomy school will expand current activities to include plastination and Thiel embalming during the academic summer break. The DI has been advised on maintaining the security or the department to maintain the dignity of the deceased during refurbishment work (advice item four).

Anatomy Hub (University of Hull)

Access for undertakers is discrete. The hub site has a specially-designed lift that allows undertakers to reverse their vehicles into it, to deliver and collect bodies and body parts. The lift opens only into the first floor embalming room and access is restricted to anatomy staff.

The main body store fridge can hold up to eight embalmed bodies and a second contingency fridge can also hold eight bodies.

Bodies for dissection are labelled with a laminated tag attached to one ear. When prosections are created, these are labelled with a code using the same number and letters to designate the nature of the prosections; for example, inclusion of the letters 'RH' denotes 'right hand'. Four fridges are used to store prosections, similar parts are stored together. Bodies in the fridge were wrapped in plastic bags and covered with white cloth; prosections are stored wrapped in plastic bags. Fridge temperatures are monitored on a regular basis.

The hub has a family room, where relatives of those who have donated their bodies can come and pay their respects prior to cremation. Following cremation, families either take ashes away at the crematorium or the establishment agrees to hold them for an indefinite period of time. Advice has been provided to the DI about the indefinite storage of ashes (advice item five).

During a fire alarm, the doors to the anatomy laboratory will allow staff and students to exit the room. To mitigate the risk of unauthorised entry into the anatomy laboratory during a fire alarm, these fire doors will not allow access into the anatomy laboratory without a swipe card.

A traceability audit of two bodies in storage and three prosections was conducted against the establishment's database and consent forms. No discrepancies in traceability were found but incomplete details had been recorded on the database. Advice has been provided to the DI about audits for records (advice item one).

Anatomy Satellite (University of York)

The main activity conducted at the satellite involves teaching using prosections. Occasionally, when required for a particular class, body dissection also takes place. In these instances, only one body is ever at the satellite at any time.

The satellite has secure access for undertakers to deliver body parts or bodies.

The anatomy laboratory is split into workstations and each workstation has designated air extraction units to prevent formaldehyde exposure.

At the time of audit, no human tissue was being stored on site as teaching had concluded for the year.

Comparative anatomy is also taught at the establishment; animal tissue is used and stored separately from human tissue.

Research Satellite (Daisy Tumour Bank, Castle Hill Hospital, Hull)

The facility has swipe card access and additional locks on the laboratories and freezers where relevant material will be stored. Each freezer has clear instructions of what to do in case of failure and a contingency freezer is kept in a separate location. All freezers are linked to two independent temperature monitoring systems and data is downloaded and audited monthly.

The satellite is also used to store samples that have been collected for research projects which have received ethical approval from recognised research ethics committees and are therefore exempted from HTA licensing. These are collected using the same procedures as will be applied to all prospectively collected tumour bank samples in the future. Samples are placed in pre-barcoded cryovials at the point of collection to mitigate loss or incorrect labelling. This system relies on placing pre-barcoded cryovials in mapped freezer trays. This facilitates electronic updating the inventory and for performing real-time traceability audits.

A traceability audit of two samples under research was conducted and no discrepancies were found.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ2	During the traceability audit, some information on the database was found to be incomplete; for example, the consent of a donor to allow the use of prosections for teaching was not recorded as on the consent form. The DI is advised to ensure that future audits include checking electronic records for completeness. As the research and anatomy staff are separated by location and activity, the DI has been advised that cross-activity audits may be conducted. Similar to audits undertaken by external colleagues, such audits may be considered useful, as the documentation and the activities do not overlap.
2.	GQ7	Although the Daisy Tumour Bank has a comprehensive set of risk assessments; the DI is advised to expand the scope of these to include the risks of receiving research samples that do not have valid donor consent for use and/or storage, and the loss of samples while being transferred from theatre.
3.	PFE1	During the impending refurbishment work at the hub, the anatomy laboratory will be accessed by non-departmental staff. The DI is advised to risk assess the security of the anatomy suite ensuring that the dignity of the deceased is maintained during this time.
4.	N/A	Following cremation, the establishment receives ashes from the crematorium for storage. The establishment does not have a policy for the length of time that ashes will be stored prior to collection by the relatives. The DI is advised to limit the length of time that ashes are stored at the establishment, so that families are encouraged to make a decision on collection, storage or disposal within a reasonable timeframe.

Concluding comments

The DI has good oversight over licensable activities conducted at the hub and two satellites.

Many areas of good practice were seen during the inspection.

- The anatomy staff have good working relationships with staff at other anatomy schools in the region (Newcastle, Leeds and Sheffield). If one anatomy school is unable to receive a donation, another will endeavour to accept.

- The establishment has robust consent seeking procedures for the donation of bodies for anatomical teaching and the donation of tissues for research. Contact details of establishment staff are provided to ensure that the patient or donor will know who to contact if they wish to withdraw their consent.

- The Person Designated at the research satellite site conducts consent training across licence.

- The anatomy staff provide support for donors and their families. Donors are encouraged to contact the department with any concerns or wishes and notes of each conversation are recorded in individual donor files. A family room and remembrance garden are provided for families to pay their respects and the establishment will store ashes until families have decided about their collection

- The DI has developed a well-considered induction training programme for first year undergraduate students. The training highlights the importance of dignity and respect towards the donors of the bodies and other material.

- The DI has conducted audits of its SLAs, which included:
    - An audit of the SLA with the undertaker who removes bodies and body parts for cremation. This involved establishment staff shadowing the undertaker from receipt of coffins at the establishment through to the collection of ashes at the crematorium.
    - An audit of the waste disposal SLA included establishment staff travelling with the waste disposal company and overseeing the incineration procedure.

Sample management at the Daisy Tumour Bank is robust and supported by a good system of document control.

The HTA has given advice to the Designated Individual with respect to governance, audits, risk assessments and storage.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 7 July 2015

Report returned from DI: 20 July 2015

Final report issued: 21 July 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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
• 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
• 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
• 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
• 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
• A document control system, covering all documented policies and standard operating procedures (SOPs).

- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- 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

GQ4 There is a systematic and planned approach to the management of records

- 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)

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- 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

GQ6 There are systems to ensure that all adverse events are investigated promptly

- 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)

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- 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 2: 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.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

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.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. 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.