Site visit inspection report on performance against HTA quality standards
Medical Teaching Unit, Sheffield
HTA licensing number 12130

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.**

5 April 2011

Executive Summary

A site visit inspection of the Medical Teaching Unit, Sheffield (the establishment) was carried out by the HTA on 5 April 2011.

The establishment was found to have met all HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Advice has been provided to the establishment for their consideration. Specific examples of strengths and good practices are included in the concluding comments section of the report.

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.

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

The Medical Teaching Unit (MTU), at the University of Sheffield, mainly carries out the storage and anatomical examination of human cadavers. Approximately 50 donated bodies are accepted into the MTU each year. The donors are typically people from the local area who have completed a consent form for the bequeathal of their body for anatomical examination, education, training and research following their death. The MTU also works with anatomy facilities located in Manchester and Nottingham, to refer a small number of donors if there is a logistical reason why they cannot be accepted at one facility, or if there is a surplus of donors in one area.

The MTU is used to teach human anatomy to approximately 250 medical students, 80 dental students and a smaller number of biomedical students. Qualified doctors and surgeons also use the facility for professional training.

Embalmed cadavers are stored in a refrigerated body store, with capacity for 50 cadavers, until they are required for anatomical examination. A number of embalmed or plastinated prosections, as well as human bones, are stored within locked display cabinets in the MTU. The establishment also has a facility to plastinate its own prosections.

A routine inspection was carried out, comprising a visual inspection of the dissection room, embalming room and body store, interviews with members of staff, documentation review and an audit trail. An audit trail was conducted in the body store, where the details on the identity tag of one of the cadavers was verified against the corresponding details held in the register of donors, consent documentation and acceptance records. A similar audit trail was completed for a cadaver, a part of a cadaver and a retained embalmed specimen in the dissection room. 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. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

All applicable HTA standards were assessed as fully met during the on site inspection of the Medical Teaching Unit, Sheffield.

Advice

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

No.	Standard	Advice
1.	C2	The bequeathal booklet provides information at a suitable level of detail to enable donors to give valid consent. The DI should consider increasing the size of the font used in the booklet to make it easier for people with poor eyesight to read.
2.	GQ2	Standard operating procedures (SOPs), policies and forms are reviewed on an annual basis; however the date when these documents are reviewed is not recorded. Documents which do not require amendment following review remain

		on the same version. Consequently, in the absence of a documented review date or version change, some of the governance documents outwardly appear to be overdue for review. The DI is advised to document the date when standard operating procedures (SOPs), policies and forms are due for review and the date when they are reviewed.
3.	GQ2	The DI is advised to implement a regular system of procedural audits to ensure SOPs accurately reflect the practices being carried out. The establishment may benefit from involving members of staff who do not normally work within the dissection room to complete the audits. The DI is also advised to implement a regular audit of the dates by which the cadavers must be disposed of to ensure that these dates are not exceeded.
4.	GQ4	The DI is advised to ensure that correction fluid is not used in donor records. Any errors in documents should be corrected by a single line through the mistake, the correct information written and then initialled and dated.
5.	GQ7	Assessments have been made of the risks to health and safety of staff, students and visitors. The DI has also identified areas where problems may arise and solutions to these problems, for example the actions to take if the body of a deceased person arrives without appropriate paperwork. The DI is advised to build these into formalised risk assessments.
6.	PFE3	The DI is advised to consider a more formalised system of monitoring and recording the temperature of the body store fridges. Since most of the cadavers stored within the fridges are embalmed, the risk to the integrity is generally low. However, if a non-embalmed body is being stored or the facility is closed for longer periods, additional monitoring which is recorded would be advisable to ensure that the body of the deceased is being maintained under appropriate storage conditions.
7.	PFE3	When a body is received with insufficient paperwork or erroneous details it prevents the establishment staff proceeding with the normal acceptance and preparation processes. The DI is advised to document the maximum time period that a non-embalmed body can be kept within the body store.

Concluding comments

During the inspection of the MTU, several areas of good practice were noted. The Register of donors is very clearly laid out, containing all the details of each donor, and including columns to record which Act was in force when the consent was taken, whether tissue may be retained indefinitely and whether photographs may be taken.
The MTU has a very good system of governance. There is a dedicated focus group called CUTIT (Committee for the Use of Tissue In Teaching) which meets on a regular basis to discuss issues within the MTU, matters relating the HTA licence and to review quality documents. All the procedures carried out in the MTU are documented as concise SOPs. Records audits are regularly completed to check that all retained specimens are accounted for, to ensure that there is the relevant permission to retain parts and to verify the identities of cadavers against the paper records.
The facilities are purpose built, with a dedicated teaching area, dissection room and several smaller rooms adjoining the main dissection room for smaller study groups. The establishment accepts a large number of cadavers each year and has to be well organised to maintain traceability of all body parts as they become dissociated and to ensure the cadavers are used in the most logical order to prevent them exceeding their date for disposal.

Once anatomical examination of the cadaver is complete, the establishment staff arrange for the remains to be cremated (unless the donor or family have requested a private cremation or burial). An annual service of remembrance and thanksgiving is held, which is well attended by staff, students and family members. The names of the donors are also entered into an elegantly laid out book of remembrance. The DI has sought to ensure any retained anatomical specimens are also disposed of sensitively. An agreement is in place with the local crematorium which permits the cremation of body parts providing certain legal documents are submitted, such as a copy of the death certificate, and information on the prior cremation or burial of the body.
Although no shortfalls were identified during the inspection, the establishment has also been provided with advice in a number of areas, which the DI is advised to consider.

Report sent to DI for factual accuracy: 13/04/11

Report returned from DI: 26/04/11

Final report issued: 06/05/11

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
• 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 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.