Site visit inspection report on performance against HTA quality standards
Brighton and Sussex Medical School
HTA licensing number 12098

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.**

02 November 2010

Executive Summary

A site visit inspection of Brighton and Sussex Medical School (the establishment) was carried out by the HTA on 2 November 2010.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Some shortfalls were found, particularly in relation to GQ2, PFE3 and D2. Any particular examples of strengths or good practice 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

Brighton and Sussex Medical School (BSMS) carries out anatomical examination of approximately 25 embalmed cadavers as part of undergraduate and postgraduate courses each year. A separate anatomy establishment takes donor consent and records whether donors consent to storage and use for a specified period or indefinitely and whether photographs may be taken or not. The deceased are embalmed prior to being transported to BSMS. Qualified clinicians also occasionally use the facilities for surgical training courses using fresh frozen cadaveric parts imported from America. An agreement between the American company and the course organiser ensures that consent is obtained in line with local legislative requirements and a copy is provided to BSMS. These courses are organised by independent course organisers and the BSMS only takes responsibility for the storage of the cadaveric material once it has been received on the premises.

The HTA undertook a routine inspection of the BSMS Anatomy Laboratory, which included the main dissection room, a storage area with refrigeration unit for storage of embalmed prosections and freezer for storage of fresh frozen cadaveric material.

An audit trail was carried out on the identifying numbers of three donors. The unique identification number for each of the donors was recorded in the Cadaver Information Book along with the name, age, gender and date of death, date of receipt and the date of disposal of the deceased. These details were compared with the identification tags on the ear and ankle of two cadavers and the prosected specimens retained from the third donor. The details were also traced to consent forms and in the case of the third donor the disposal record for the cadaver from which the prosections have been removed. The records provided full traceability of cadavers, prosections and frozen cadaveric material and were found to correspond accurately with consent provisions. Some minor discrepancies with dates were noted in the disposal records for retained prosections. A records audit was also completed on the photographic inventory of existing holdings of potted specimens and bones and no discrepancies 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).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	Formal audits of procedures are completed and documented. The establishment also undertakes interim checks to ensure completeness of records and to account for all specimens. These interim checks should also be documented so that any minor discrepancies that occur frequently can be identified and action can be taken to prevent reoccurrence.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Embalmed prosections are stored for longer periods in fridges for additional protection against deterioration and imported cadaveric specimens are currently stored in a freezer no longer than a few days prior to usage. The temperature of the fridges and freezer are regularly observed, however the temperatures are not routinely recorded to allow trend analysis. This would ensure that the tissues, particularly frozen cadaveric specimens, are being stored in a suitable stable environment. The normal working temperature range and action to be taken if out of range is not documented. This would allow equipment failure to be identified by any member of staff and ensure appropriate measures are taken in the most efficient way, so that deterioration of cadaveric specimens is prevented.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	On occasion, specimens or prosections are separated from a cadaver and loaned to another department or anatomy school. It is not clear in the disposal SOP whether a cadaver can be released to the funeral director without these specimens having been returned. Tissues are only being retained for longer periods if the donor gave their consent; however, a clear process will ensure that disposal reflects the terms of the consent given. The date recorded as relating to disposal varies from the date the cadaveric material is placed in the clinical waste bin, to the date the clinical waste company collect it, or the date it is incinerated, and is therefore not standardised.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to ensure that the donor testing carried out for fresh frozen cadaveric specimens meets the recommended guidelines as detailed in the HTA 'Policy on the import of fresh frozen bodies and body parts' and the HSE documents 'Controlling the risk of infection at work from human remains'.

Concluding comments

Brighton and Sussex Medical School has several areas of good practice. The premises are relatively new (opened in 2003), with a good layout, regularly maintained equipment and kept to a high level of cleanliness. There is a high awareness of the need for security and the premises are well secured with key and code locks, an alarm, as well as CCTV. Staff at the BSMS show dignity and respect towards the deceased at all times and this ethos is instilled in students through lectures where the Human Tissue Act 2004 is discussed, an introductory presentation in the Anatomy Laboratory and by the requirement that each student signs up to a code of conduct. The policies and procedures carried out by the BSMS staff in the Anatomy Laboratory are documented and assessments have been completed of the risks to health and safety of staff, students and visitors, as well as the risks to the cadavers and prosections of loss or lack of traceability. The BSMS has restricted the number of students to a maximum of 80 at any one time to ensure that there is sufficient space for anatomical examination to be carried out safely and efficiently. Records of the cadavers and other specimens were clear and accurate and the establishment staff carefully adhered to the wishes of the donor with regard to the time limit on storage and use of the cadaver and whether photos may be taken. Three minor shortfalls were identified during the inspection and these relate to the need for

standardisation of practice in one area and the lack of fully recording the procedures which the establishment staff have been carrying out. These are noted above.

Report sent to DI for factual accuracy: 15 November 2010

Report returned from DI: 16 November 2010

Final report issued: 7 December 2010

Once the establishment has been able to comment on the factual accuracy of the report, it will be published on the HTA website.

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan.

Date: 11 January 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
• 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.