Site visit inspection report on performance against HTA quality standards
The University of Birmingham, Medical School
HTA licensing number 12236

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.**

25 July 2013

Executive Summary

A site visit inspection of The University of Birmingham, Medical School (the establishment) was carried out by the HTA on 25 July 2013.

The establishment was found to have met all HTA standards. Advice and guidance is provided in a number of areas where the HTA identified opportunities for improving existing systems and procedures. Examples of strengths and 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.

Background to the establishment and description of inspection activities undertaken

The establishment is an undergraduate and postgraduate teaching facility within The University of Birmingham School of Medicine. Donated bodies are used for the purpose of anatomical demonstration to first and second year degree students from the schools of medicine and dentistry, and to educate and train health care professionals as part of graduate and postgraduate courses. These courses include Master of Science and courses for Ear, Nose and Throat (ENT) surgeons.

The licensed premises comprise a dissection room, incorporating a dissection area and a preparation area, a 'prosectorium' with associated locker room and changing area, and eleven anatomy seminar rooms. The prosectorium is of modern design having been built in 2008. There are ten stainless steel tables in the prosectorium, each incorporating downdraft extraction. The design of the tables and the room includes readily washable equipment and surfaces and provision to minimise build-up of contamination through the use of coved floor to wall junctions. In contrast, the dissection room is of an older design and is in need of regular reviews to maintain the integrity of fabric and finish. Advice is offered regarding the benefit of, periodic, 'fresh eyes' review of this area to enhance the rolling programme of maintenance (please refer to advice item 3).

The establishment operates a bequeathal process and obtains donated bodies and specimens from donors who fit established eligibility criteria. The establishment is therefore involved in the process of obtaining consent in accordance with HTA's consent standards. The establishment is also responsible for the respectful disposal of specimens in accordance with HTA's disposal standards.

This is the first on-site, routine, inspection of the establishment by the HTA. The timetable for the inspection was developed with due consideration of the results of desk-based assessments at the time of initial licence application and during the June 2011 self-assessment required under HTA Directions, and pre-inspection discussion with the Designated Individual (DI). Before the Human Tissue Act came into force, previous inspections were carried out by HM Inspector of Anatomy with the last such inspection conducted during 2006.

The scope of this inspection included visual inspection of the facilities, review of relevant documentation and interviews with members of staff undertaking licensable activities. The inspection also incorporated a number of traceability audits selected to encompass different types of specimens. Records relating to cadaveric material were checked against the establishment inventories and the respective bequeathal records. All specimens were fully traceable. There was one minor anomaly associated with the description of a plastinated specimen within its relevant file. Advice is offered regarding the most appropriate way of correcting the documentation (please refer to advice item 4).

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.

Please note that as this inspection identified no shortfalls against HTA standards there is no requirement for a corrective and preventative action plan.

Advice

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

No.	Standard	Advice
1.	GQ1	Although the making and displaying of images falls outside of the scope of the Human Tissue Act 2004, the DI is advised to update standard operating procedures 0.3 and 0.4 and the student induction presentation to reflect the principles set out in the General Medical Council's guidance regarding the use of photographic images.
2.	GQ1	The DI is advised to reinforce the existing standard operating procedure(s) on disposal by producing a policy document setting out the establishment's policy for disposal of anatomical specimens, former anatomical specimens and body parts.
3.	GQ2	The DI is advised to update the audit procedure to include a routine requirement to summarise the outcome and any recommendations arising from each audit. Where the need for corrective or preventative actions is identified, the procedure should require a timeframe for action and identify a person responsible for the corrective and preventative action.
4.	GQ2	The DI is advised to schedule a plan of audits to include a 'fresh eyes' review of the fabric and finish of the areas in which licensable activities take place. The aim of this audit should be to identify areas requiring rolling maintenance and refurbishment.
5.	GQ5	The DI is advised to annotate the establishment's records relating to the plastinated specimen selected during the traceability audit. The description of the specimen is not accurately recorded within the relevant file. As the anomaly is clear from inspection of the specimen it is considered appropriate to update the record in a manner that does not obscure the original entry.
6.	PFE1 & PFE5	The DI is advised to review the equipment, fabric and finish of the dissection room. For example, porous materials and surfaces should be avoided or suitably sealed to minimise the risk of contamination and to facilitate cleaning.

Concluding comments

The HTA found the Designated Individual (DI), the Licence Holder, the premises and the practices to be suitable in accordance with applicable HTA standards and the requirements of the legislation.

A number of strengths and good practices were identified during the inspection.

The DI, and members of the team involved in licensable activities, apply a sound approach to overall governance with an emphasis on maintaining the dignity and respect of deceased donors and to maintaining accurate records of body donations and their use. The bequeathal process is well established and is the subject of robust and considerate systems of oversight and control through a dedicated Bequeathal Secretary and Deputy. There is good use of the role of 'Persons Designated' to maintain oversight of licensable activities in line with applicable HTA standards and codes of practice. The governance arrangements include provision of a 'Human Tissue Act University Coordination Group'. There is evidence of good communication and effective cohesion across the members of staff involved in licensable activity.

Members of staff involved in licensable activities demonstrate a good knowledge and understanding of the practical application of the HTA anatomy sector requirements and, where applicable, have established good links with third parties whose services are relied upon as part of the overall process. There is evidence that the Bequeathal Secretary and Deputy put a high emphasis on the quality and content of communications with donors, donors' families, General Medical Practitioners and other healthcare professionals. There is a long established working relationship with a local firm of funeral directors.

Access to the different areas of licensed premises is well controlled. The standard of design, fabric and finish applied to the prosectorium during its construction in 2008 has resulted in a robust facility that continues to, comfortably, meet user requirements.

A number of pieces of advice have been provided to the DI where the HTA identified opportunities for improvement to existing systems and procedures.

Report sent to DI for factual accuracy:	**21 August 2013**
Report returned from DI:	**3 September 2013**
Final report issued:	**10 September 2013**

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

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

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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.