Site visit inspection report on performance against HTA quality standards
Swansea University
HTA licensing number 12389

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.**

1 May 2013

Executive Summary

A site visit inspection of Swansea University (the establishment) was carried out by the HTA on 1 May 2013.

The establishment was found to have met all applicable 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.

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

Background to the establishment and description of inspection activities undertaken

The establishment is an undergraduate and postgraduate teaching resource within Swansea University College of Medicine. Donor bodies are used for the purpose of anatomical demonstration at the College of Medicine and used to educate and train health care professionals as part of a postgraduate Masters Degree course.

The licensed premises comprise a prosection room, an anatomy laboratory, a clinical pathology laboratory and an anatomy seminar room

The establishment does not operate a bequeathal process and obtains donated bodies and specimens 'on loan' from two HTA licensed university schools of anatomy. The establishment is therefore not involved in the process of obtaining consent and, hence, a review of consent procedures was not included within the scope of this inspection. However, as part of the loan procedures, members of staff are provided with the opportunity to verify that appropriate consent has been obtained prior to any loans. Similarly, the establishment does not dispose of any cadaveric material as the loan procedures require the return of the body or specimen to the loaning establishment. A review of disposal procedures was therefore not included within the scope of this inspection. The loan procedures are the subject of formal agreements between the relevant licensed establishments and this establishment.

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 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 retained specimens. Records relating to cadaveric material were checked against inventories and any relevant records of transport and delivery between the provider and the establishment. All specimens were fully traceable. Two minor anomalies associated with the description of loan specimens were addressed by the establishment during the traceability audit. The traceability audit also identified that, although members of establishment staff are provided with an opportunity to verify that appropriate consent has been obtained prior to collection of any loans, this is not always carried out.

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.

Advice

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

No.	Standard	Advice
1.	C1	The Designated Individual (DI) is advised to implement a formal system whereby a verification step to confirm that appropriate donor consent has been obtained is included as a routine part of the loan collection procedure. The formal introduction of this step is in line with the process described within the material transfer agreements.
2.	GQ1	The DI is advised to update the standard operating procedure (SOP) relating to use of the 'Swansea University Specimen Transport' proforma to include reference to the minimum level of information required. This should ensure that consistent type and level of information is recorded regardless of which member of staff completes the form.
3.	GQ2	The DI is advised to apply the process of document revision control that was implemented during the May 2012 review of SOPs to all policies and procedures relating to licensable activities. This will ensure that only the most current approved documents are in use and provide an audit trail of the review of these documents, the approval of any changes and the reason for change.
4.	GQ5	The DI is advised to update the SOP relating to traceability of bodies and body parts to include reference to steps to be taken to maintain traceability when relevant material needs to be temporarily relocated. For example, in the event of an unforeseen incident such as malfunction of a refrigeration unit.
5.	GQ7 & PFE3	There are good systems in place to minimise risk of damage or theft and assure the security of holdings. The DI is advised to extend the programme of periodic documented risk assessments to reflect the informal risk assessments that have been conducted in relation to: • the external perimeter of the building to verify that existing levels of security and the existing coverage of closed circuit television monitoring meet expectation; • the category of access control applied by the Estates Department to the different areas where licensable activities take place. In particular, to verify that the respective level of access control meets expectation; • the provisions to protect the dignity of the deceased during transfer from and back to the loaning establishments. This should include the transfer between buildings and vehicles; • storage of existing holdings in the 'Egypt Centre' to verify that levels of security and monitoring meet expectation.
6.	PFE2	The DI is advised to update the SOP relating to cleaning of the refrigerated storage units to include the requirement for cleaning to be documented and to implement an appropriate system for retaining evidence of this activity.

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 applies a sound approach to governance with an emphasis on maintaining the dignity and respect of deceased donors and to maintaining an accurate inventory of donated material that is taken on loan from other HTA licensed establishments. 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 'HTA Committee' and there is evidence of effective use of periodic HTA Committee Meetings with a standard agenda linked to HTA requirements. There is evidence of good communication across the members of staff involved in licensable activity and with members of staff at the provider establishments. The introduction of 'duty of care' audits as part of the material transfer agreement with one provider is regarded as good practice.

Members of staff involved in licensable activities demonstrate a good knowledge and understanding of the practical application of the HTA anatomy sector requirements.

Access to the different areas of licensed premises is well controlled with good provision for the licensed premises to be monitored by security outside of standard hours. The establishment has utilised the flexibility of a proprietary access control system in order to set stricter levels of access depending on licensable activity within discreet areas with the strictest level of access control being aligned with the storage areas for donated bodies and cadaveric material. The use of tablet computers in conjunction with a dedicated server provides the means for a secure and accurate inventory of the constantly changing pieces of loaned material and is considered to represent good practice for maintaining traceability.

A number of pieces of advice have been provided to the DI where the HTA identified opportunities for improvement to existing systems and procedures. In addition the HTA is encouraged by the DI's plans to enhance the scope of the establishment's quality systems. This includes but is not necessarily limited to:

- extending the closed circuit television coverage to the central corridor serving the licensed premises;
- purchase of a dedicated vehicle for the transport of loaned material from and back to the provider establishments;
- a formal system for the annual review of SOPs and risk assessments.

The DI also plans to assign dedicated resource to quality assurance (QA) matters. Dedicated QA support would facilitate the introduction of the initiative for annual review of documents referred to above and would also facilitate some of the activities highlighted under the 'Advice' section of this report.

Report sent to DI for factual accuracy: **5 June 2013**
Report returned from DI: **17 June 2013**
Final report issued: **28 June 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

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.