Site visit inspection report on compliance with HTA minimum standards

University of Northumbria at Newcastle (School of Applied Sciences)
HTA licensing number 12482

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.**

23 July 2014

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.

University of Northumbria at Newcastle (School of Applied Sciences) (the establishment) was found to have met all 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 licences 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

The establishment stores plastinated, prosected cadavers and body parts and prosected resin mounted specimens, on behalf of St Georges International School of Medicine which is based in Grenada, West Indies.

This material is used in the anatomical training and education of students enrolled in the St George's University Keith B Taylor Global Scholars Programme, which leads to a medical qualification.

Cadavers and prosected specimens all originate from outside of the UK; copies of donor documentation are held by the establishment. The establishment also holds a limited, donated, collection of dry skeletal material, which is not currently used for teaching purposes.

The Anatomy Teaching Centre (ATC) is housed within a converted, listed building and access is restricted to registered staff and students, unless arranged with the DI. A member of ATC staff is present at all times while the facility is in use by students. Security is maintained by swipe card entry and there is CCTV coverage of the laboratory area.

An induction is provided for staff and students accessing the ATC and all staff, students and visitors must sign a Code of Practice in order to work in, have use of, or access the facility. Signed copies of these were reviewed as part of this site visit.

Relevant material is stored in a designated area of the ATC. Access to this area is limited to the DI and a Person Designated and is controlled by a lockable shutter system.

Material is anonymised and labelled with a unique identifier. All material that is removed or separated from specimens is stored in labelled containers. Larger items that have been removed, or are separated, are assigned a daughter code and added to the specimen inventory. This is so that all material remains with its originating specimen in the event of transfer or disposal.

Monthly audits of stored material encompassing presence and status of material are conducted by the DI. Advice pertaining to these audits is given below (advice item 3).

This was the second routine site-visit inspection of the establishment which was inspected previously in 2008. The current DI was appointed in 2011. The inspection consisted of interviews with the Designated Individual (DI) and CLHc, a review of relevant documentation and a visual inspection of the premises.

An audit of stored material was conducted. The unique identifiers assigned to a whole plastinated cadaver, a plastinated prosected specimen and a resin mounted specimen were cross referenced against the specimen inventory. A number of transcription errors were identified relating to the recorded location of specimens on the audit log sheet and update of the specimen inventory. These transcription errors did not affect the traceability of specimens. The DI was able to account for the location of each specimen through completion of the monthly specimen audit and the maintenance of a checklist which detailed which specimens were used for each teaching session. Advice has been given to the DI in relation to this (advice item 3).

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.	GQ1	The DI is advised to review the frequency and format of governance meetings. For example a regular virtual meeting (in the format of a standing monthly email communication) could be used to supplement meetings held in person. This may help to ensure that matters pertaining to licensable activity are recognised and documented by those staff members who have oversight of the conduct of licensable activities.
2.	GQ2/ GQ4/ GQ7	The DI is advised to implement a rolling schedule for the audit of controlled documents. This is to ensure that all documents undergo a periodic review and are updated to reflect current practices in a timely fashion. As part of this audit, the DI is advised to verify that each controlled document includes the minimum recommended controls of: • A unique identifier for all documents • The identification of the author • The version number of the document • The issue date of the document • The review date of the document

3.	GQ5	The DI is advised to refresh the Specimen inventory and audit sheet as follows: • Plastinated cadavers- the DI is advised to add the boxes of small parts that have become separated from cadavers to the specimen inventory and audit checklist and to ensure that the inventory sheet for whole cadavers is updated each time a part is removed and added to the specimen inventory. • Resin mounted specimens - the DI is advised to update the audit checklist and the specimen inventory to reflect the current storage status of specimens which are no longer intended to be transported to Grenada. The DI is also advised to introduce a reverse traceability audit to the schedule of specimen audits. This can be achieved by using the specimen inventory to locate items in the specimen store.
4.	GQ5	The DI is advised to document the establishment's policy regarding the storage of the dry skeletal material that it holds. This is to ensure that considerations regarding the use, traceability and disposal of these items are documented and subjected to periodic review.
5.	PFE3	One of the plastinated cadavers is not currently used for teaching due to deterioration of the resin coating used to delineate anatomical structures. This item has been packaged for secure storage within the ATC and a visual assessment of its condition has not been performed for some time. The DI is advised to perform periodic visual checks to monitor the condition of this specimen on an ongoing basis, in order to assess for any further deterioration.
6.	PFE4	Currently all material is retained within the facility and specimens are not transferred elsewhere for any reason. In the event that this should change, the DI should increase the scope of the specimen movement control to reflect agreements in place relating to the transfer and, transport and packaging arrangements.
7.	D1	The DI is advised to incorporate the statement on disposal of material into the establishment's operation manual. This statement is currently a stand-alone document.

Concluding comments

Examples of good practice were observed during this site visit inspection. A well-considered security system ensures oversight of personnel within the facility, and the DI has close oversight of access to relevant material.

Care and respect for specimens was demonstrated through both their storage and ongoing consideration regarding the ways in which they may continue to be used. This ethos is instilled in visitors and students. For example an enlarged copy of the ATC Code of Practice is displayed in the entrance of the facility to serve as a reminder to students of their obligations and responsibilities.

The HTA has given advice to the Designated Individual with respect to governance meetings, governance documents, specimen inventory and audit and policy review.

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

Report sent to DI for factual accuracy: 19 August 2014

Report returned from DI: 28 August 2014

Final report issued: 2 September 2014

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.

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.