Site visit inspection report on performance against HTA quality standards
Anatomy and Clinical Skills, Newcastle University
HTA licensing number 12148

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.**

28/29/30 June 2011

Executive Summary

A site visit inspection of Anatomy and Clinical Skills, Newcastle University (the establishment) was carried out by the HTA on 28, 29 and 30 June 2011.

The establishment was found to meet almost all of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. A minor shortfall was identified in relation to governance and quality systems. 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 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment comprises a hub facility at Newcastle University and 3 satellite facilities at:

- Durham University, Queen's Campus
- Freeman Hospital, Newcastle Surgical Training Centre
- James Cook University Hospital, Temporal Bone Laboratory

The establishment is a major undergraduate teaching resource within both the Faculty of Medical Sciences at Newcastle University and the University of Durham, School for Health at Queen's Campus, Stockton. In addition, the establishment provides postgraduate training facilities for the teaching and education of medical professionals.

The licensed premises at Newcastle University comprise a dissecting room, a continuing professional development (CPD) laboratory and an embalming and storage area. Adjacent to these are an associated clinical skills laboratory, storage rooms, a museum room and technical support rooms. Donor bodies are used for the purpose of anatomical examination at the medical school and used to educate and train medical, dental and allied health care students.

The hub at Newcastle University also provides anatomical specimens to its satellite facility at Queen's Campus, Stockton, where undergraduate medical students study anatomy during the first two years of their medical training at Durham University.

The hub at Newcastle University also supplies cadaveric material to the Newcastle Surgical Training Centre at the Freeman Hospital. This unit serves as a major teaching resource for surgical training, education and professional development.

Temporal bones from bodies accepted for anatomical examination by the hub facility at Newcastle University are used for ear, nose and throat training purposes by surgical trainees at the Temporal Bone Laboratory, James Cook University Hospital, Middlesbrough.

This is the first on-site, routine, inspection of the establishment by the HTA. The timetable for 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 2005.

The scope of this inspection included visual inspection of the hub and the three satellite facilities, review of relevant documentation at each facility and interviews with members of staff undertaking licensable activities. The review of each facility included a traceability audit. Records relating to cadaveric material were traced back to evidence of consent and checked against inventories and any relevant records of transport and delivery. The traceability audit extended to records relating to specimens that have been respectfully disposed of. All specimens were fully traceable. A discrepancy in the audit trail at one of the satellite facilities is reported as a minor shortfall. This shortfall is detailed under GQ5. The traceability audit also identified some inconsistencies in the way specimen containers are labelled when comparing the hub at Newcastle University with the satellite facility at Queen's Campus. This has resulted in advice being offered under item 6 of the advice section.

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
GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The inspection of donor records at the Newcastle Surgical Training Centre, Freeman Hospital, identified one recent occasion when a donated body was received and released for use prior to receipt of all the required paperwork. During the inspection this event was discussed with staff who stated that the existence of the required paperwork was confirmed by telephone and that the body was released for use pending receipt of the required paperwork. However, the telephone conversation and reasons for delay in receipt of the required paperwork were not documented. In addition, the relevant standard operating procedure does not describe circumstances under which a body may be released for use pending receipt of the required paperwork. At the time of inspection this event was not documented as a deviation from standard operating procedure. It is noted that all necessary paperwork was in place at the time of inspection. However, without the documented evidence of the telephone conversation, there was an unexplained discrepancy in the audit trail.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised that document control systems across all four facilities should include 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 The inspection identified that these elements of document control are already in place across the majority of areas. However, the inspection also identified isolated examples of documents which did not include all of the above elements of document control.

2.	GQ1	The DI is advised to revise the documents entitled: “Rules for Using Temporal Bone Laboratory” and “Critical Incident Policy” which are in use at the James Cook University Hospital, Temporal Bone laboratory. Revision should include a reference, in each document, to the fact that the Temporal Bone Laboratory is licensed under the Human Tissue Act 2004.
3.	GQ3	The DI is advised to use the experience gained through the induction and training programme within the Newcastle Surgical Training Centre to develop a training module for the benefit of future new starters.
4.	GQ4	The DI is advised to review the input of data to the new computer database at Newcastle University to ensure consistency. The inspection identified some inconsistency in the use of the dropdown menu of the system which is used to define the category of relevant anatomical specimen and some inconsistency in the amount of detail that is recorded against each entry. It is recognised that the system is in the initial phase of use which involves manual entry of current and historical data prior to routine practical use. Tight procedural control on the input of data will ensure that the system fully meets user requirements once it is in routine use.
5.	GQ4	The DI is advised to make provision for records that are held on the computer system at the Queen’s Campus to be retained on the drive associated with the mainframe, University, computer. This will ensure that these records are subject to regular, automated back-up procedures which will allow recovery in the event of local system failure.
6.	GQ5	The DI is advised to review the specimen identification system for the specimen containers used at Newcastle University. Review of the facilities at Newcastle University identified inconsistent standards of specimen identification as applied to the outside of specimen containers. In some cases there was insufficient information to allow the determination of contents without the need to open the specimen container. The inspection identified that the system in use at the Queen’s Campus facility proved more robust and reliable than that in use at Newcastle University.
7.	GQ7	The DI is advised to extend the programme of risk assessment to include formal assessments of the risk to anatomical specimens as a result of licensable activities. The inspection identified that the Queen’s Campus facility has carried out formal risk assessments of practices and processes taking place under the licence. The other facilities would benefit from an equivalent extension to their risk assessment process. The formal process of risk assessment should include, but may not necessarily be limited to: • Premises, practices and processes that are connected with licensable activities • The potential for loss of or damage to or misidentification of donated material.
8.	GQ7	The DI is advised to conduct a formal risk assessment of the transport arrangements relating to the collection and delivery of temporal bone specimens that are used at James Cook University Hospital, Temporal Bone Laboratory.
9.	PFE2	The DI is advised to consider introducing a clear line of demarcation at the threshold of the storage area within the Newcastle Surgical Training Centre. The demarcation should alert those using the facility that they are entering a transition zone.

Concluding comments

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

The DI has a wealth of relevant experience, a working practical knowledge and a full understanding of the licensable activities being conducted at all of the premises operating under the establishment's licence. The DI demonstrates an excellent knowledge and understanding of the HTA anatomy sector requirements and the inspection identified many areas of practice where the DI has assessed licence requirements, developed ways of working and influenced and promoted compliance with licence requirements.

Access to the various licensed premises is documented and well controlled. Students accessing the facilities at Newcastle University and the University of Durham Queen's Campus are well supervised. Prior to entering the facilities students are required to attend an introductory lecture which details the background to the Human Tissue Act 2004 and the involvement of the HTA. Students are required to sign a declaration regarding the local code of conduct which reflects the requirements of the Human Tissue Act 2004 and the HTA code of practice on anatomical examination.

Staff involved in licensable activities demonstrate a strong commitment to meeting and maintaining HTA standards. There is good communication across the teams involved in licensable activities. The DI has a sound approach to governance. There is good use of the role of 'Persons Designated' to maintain close oversight of activities at the hub and satellite facilities. The establishment has also benefitted from a dedicated quality management advisor. The DI and team have regular meetings that address HTA matters.

The establishment places a high emphasis on maintaining respect, dignity and confidentiality in relation to donated anatomical specimens. The bequeathal process is well established and is the subject of robust systems of oversight, control and documentation via a dedicated Bequeathal Secretary.

Report sent to DI for factual accuracy: 21 July 2011

Report returned from DI: 2 August 2011

Final report issued: 1 September 2011

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

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.