Site visit inspection report on performance against HTA quality standards
UCL Ear Institute
HTA licensing number 12161

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **storage of an anatomical specimen;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose.**

5 May 2011

Executive Summary

A site visit inspection of UCL Ear Institute (the establishment) was carried out by the HTA on 5 May 2011.

The establishment was found to meet most of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. A number of minor shortfalls were found in relation to the establishment's governance and quality systems. Although the establishment has not carried out any anatomical training events since it was licensed by the HTA, it holds collections of former anatomical specimens and other material for the purpose of research, education or training. This aspect of the establishment's work was the main focus during this site visit inspection and requires an adjustment to their licensing status.
Examples of strengths 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 UCL Ear Institute was established in the late 1940s as part of the British Post Graduate Medical Association programme. This programme was introduced with the aim of developing training facilities to benefit the teaching and education of medical professionals.

Prior to obtaining a HTA licence, the establishment ran courses aimed at the teaching and appraisal of temporal bone dissection by trainees at the Royal National Throat, Nose and Ear Hospital. It was principally with this activity in mind that the establishment obtained a HTA licence in 2007. The establishment has not carried out any anatomical training events since it was licensed by the HTA. It is likely that these training events may be reinstated in the future. In the meantime, former anatomical specimens have been retained for potential use for research or education or training.

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. 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 establishment's licensing history and pre inspection communication with the Designated Individual.

In addition to former anatomical specimens, the establishment holds an archive collection of temporal bones sections and related tissue dating back to the 1950s and 1960s and a collection of plastinated skull specimens dating back to the mid-1990s. These collections have sound provenance, supported by a relevant documentation. These existing holdings may be used to support local research needs and have the potential to be a rich source of reference material for researchers based elsewhere. As a result of their potential use to support research, these archive collections need to be formally encompassed within the HTA's licensing framework through the addition of a third licence covering: 'The storage of the body of a deceased person, or relevant material which has come from a human body, for use for a Scheduled Purpose'. This additional licence, which will not impose an additional cost, will address the ongoing storage of material for research or education or training. *Post inspection note: this additional licence has been issued to the establishment in the time between the site visit inspection and the issue of the inspection report.*

The scope of this inspection included a review of the premises housing the archive collections and a review of the teaching laboratory that is set aside for courses in temporal bone dissection. During this review a traceability audit of retained former anatomical specimens was conducted. The audit identified a gap in the audit trail relating to a small proportion of former anatomical specimens. This shortfall is detailed under GQ5.

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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Practical procedures are in place for the majority of licensable activities. However, the formal documentation of these procedures is underdeveloped. In particular there is a shortage of formal, approved and authorised procedures documenting the standard ways of working for: • identification, storage and security of specimens and premises • management and control of the inventory of specimens • record management • risk assessment • audit • the management of adverse events • disposal Formal procedures, issued under change control, will establish approved, consistent and reproducible ways of working across licensable activities. (Further advice against this shortfall is provided within the 'Advice' section below).	**Minor**
GQ2 There is a documented system of quality management and audit.	The establishment's quality management system is underdeveloped in that a formal framework of policies and procedures, covering licensable activities, has yet to be implemented. There is no overarching document which provides an overview of the establishment main purpose, its organisation and structure and its approach to governance and quality. A formal quality management framework will establish minimum expectations relating to standards of governance and quality and will facilitate continuous and systematic improvement. (Further advice against this shortfall is provided within the 'Advice' section below). In the absence of a formal quality management system there is no formal schedule of audits in relation to stored material, records, policies or procedures. Any reviews that have been conducted to date have been ad hoc and informal.	**Minor** **Minor**

GQ4 There is a systematic and planned approach to the management of records.	There is evidence of a sound approach to the retention of records. Records are held securely and in a manner that protects their integrity. However, the establishment's approach to the management of records is underdeveloped. The various records and forms and their control and management are not formally described in Standard Operating Procedures.	**Minor**
GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The traceability audit identified a weakness in the audit trail of tissue held in the dissecting laboratory. The current system is not robust in that it was not possible to directly correlate all of the retained former anatomical specimens with the inventory of retained tissue held by the DI. Whilst the number of retained specimens matched the number of specimens listed in the inventory, inadequate labelling of a small proportion of the specimens did not allow definitive reference to items on the inventory.	**Minor**
GQ6 There are systems to ensure that all adverse events are investigated promptly.	The establishment's systems and processes for dealing with adverse events are underdeveloped in that there is no formal procedure detailing how an adverse event is logged, reported, addressed and monitored.	**Minor**
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The system of risk assessment is underdeveloped in that there have been no formal risk assessments of licensable activities and there is no formal schedule for the ongoing review and / or update of risk assessments. (Further advice against this shortfall is provided within the 'Advice' section below).	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	In developing and implementing a formal document control system, the DI is advised to include the following elements of review and change control: • Issue number • Issue date • Author • Reviewer (the reviewer should have knowledge of the relevant procedure / process and may not need to be more senior than the author) The DI is advised to review the establishment's current activities and associated

		ways of working to identify those areas that would benefit from a documented SOP or SOPs. These should include but may not be limited to the activities itemised under 'GQ1' above. In the event that the establishment reinstates a programme of anatomical training the DI is advised to conduct another, prospective, review exercise to ensure that additional activities are the subject of formal SOPs.

2.	GQ2	In developing and implementing a quality management system the DI is advised to create a quality manual (QM). The QM should be accessible to all staff involved in licensable activities and provide a practical overview of the establishment's activities. It should act as a resource, referencing the establishment's approach to governance and quality and related policies and standard operating procedures (SOPs). The QM could be either be in paper or electronic format and may include, but not necessarily limited to, the following:
		• An introduction, outlining the purpose of the QM, the scope of the QM and the features of the establishment's governance and quality systems
		  ○ A section akin to a 'mission statement' including main responsibilities
		  ○ An overview of functions and activities
		  ○ An overview of the structure and intent of policies, SOPs and the document control system
		  ○ Organisation charts to include titles and reporting relationships
		• A statement or statements demonstrating the establishment's intent to conform to the requirements of regulatory and professional bodies, for example through adherence to standards, codes of practice, professional guidelines
		• Reference to processes relating to staff training, appraisal and continuous professional development
		
		In the event that the establishment reinstates a programme of anatomical training, the DI is advised to revisit the QM to ensure that additional activities are fully described.

3.	GQ7	The DI is advised to establish and implement a formal process of risk assessment that includes, but is not necessarily limited to: • Premises, practices and procedures that are connected with licensable activities • Any control measures that have been implemented to safeguard the integrity of specimens; for example, specific storage conditions and security arrangements • The potential for loss of or damage to or misidentification of donated material
4.	GQ5 and PFE3	The DI is advised to compile a master inventory of the individual archive collections which should form the basis for future access, inventory control and audit. In compiling a master inventory the DI is advised to revisit the storage areas to allocate designated storage locations for the different categories of specimen and link these locations to the master inventory. This exercise should result in more effective use of the available storage space and will facilitate speed of access to the stored specimens.

Concluding comments

Overall, 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. The DI and staff at the establishment are committed to quality review and improvement in order to meet

HTA standards and safeguard the valuable collections of specimens. The premises are secure and access to the specimens is well controlled and monitored. The detailed provenance of the collections is retained through the DI and establishment staff ensuring that documentation held in support of the collection is securely stored. HTA endorse the establishment's plans to better catalogue the collection so that it may be more extensively utilised.

Report sent to DI for factual accuracy: 27 June 2011

Report returned from DI: No factual accuracy comments were made by the DI

Final report issued: 18 July 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

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.