

**Site visit inspection report on compliance with HTA minimum standards**

**UCL Department of Anatomy and Developmental Biology**

**HTA licensing number 12120**

**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 September 2014**

**Summary of inspection findings**

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

Although the HTA found that UCL Department of Anatomy and Developmental Biology (the establishment) had met the majority of the HTA standards, one minor shortfall was found with regard to the Governance and Quality Systems (GQS) standards. The shortfall was in relation to governance meetings. Advice has also been given relating to the GQS, Premises, Facilities and Equipment (PFE) and Disposal (D) standards.

Particular examples of 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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**

This report refers to the activities carried out by UCL Department of Anatomy and Developmental Biology (the establishment). This was the second site visit inspection of the establishment since it was issued an HTA licence in August 2007. It was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. The previous site visit inspection was carried out in November 2007.

### Consent

The establishment is licensed for the storage and anatomical examination of human bodies and body parts, and the storage of human tissue for education or training relating to human health ('teaching') and research in connection with disorders, or the functioning, of the human body ('research'). Approximately 50 donated bodies are accepted for undergraduate and postgraduate courses each year. All consent procedures for body donation, consent information and consent training are organised by the London Anatomy Office (LAO), which is contracted to and overseen by the London and South East Committee of Anatomists (LSECA). The LAO consent form covers bequeathal of the body (and any separated parts) for anatomical examination, education, training and research. The form also records whether donors consent to storage and use for a specified period or indefinitely, and whether photographs may or may not be taken.

The establishment also occasionally receives former anatomical specimens directly from other HTA-licensed premises. There are agreements with such organisations to ensure that appropriate consent and safe transportation are in place.

Whole bodies and prosected material are used for teaching human anatomy to medical students in year 1 (general cadaveric dissection, thorax and abdomen prosection) and year 2 (head and neck, and neuroanatomy prosection). Approximately 300 medical students and a smaller number of biomedical sciences and physiological science students use the facility. The establishment organises revision sessions for clinical students and external courses for undergraduate and postgraduate medical training. Qualified surgeons, osteopaths, nurses, physiotherapists, anaesthetists and military clinicians also use the facility for professional training. Postgraduates also carry out research projects and anatomical projects within the facility.

### The facilities

The deceased are embalmed within the facility. There is an agreement between the LAO and a funeral service for the safe transport of cadavers to the establishment and their eventual burial or cremation (if either of these is required). Large prosected specimens, where consent is in place enabling retention for longer than the originating body, will also be cremated. Small separated body parts and prosections, consented to be retained for longer than the originating body, are sensitively disposed of by incineration by the disposal contractor under an agreement with the establishment.

Embalmed bodies and large prosections are stored at room temperature on trays in the well ventilated body store, which has a capacity for 20 bodies. Separated body parts awaiting prosection are stored in a refrigerator or in a -20°C freezer. Smaller prosections and those requiring wet storage are stored in appropriate humidified storage cabinets or in stainless steel chest containers.

The dissecting room contains 20 dissecting tables (with 8-9 students allocated to each table) along with a tissue collection of preserved pathological specimens (approximately 200) for teaching purposes.

There are separate storage rooms for the osteology collection (containing approximately 200 bone specimens), neuroanatomical specimens (approximately 200 specimens), paediatric and foetal specimens (approximately 1000) and tissue blocks and slides (approximately 1000 specimens). There is a separate room for animal anatomical specimens (approximately 1000).

### Loans

The establishment occasionally loans anatomical and former anatomical specimens to unlicensed organisations. The HTA loan authorisation template is used and there is full traceability for such specimens.

The site visit inspection of the hub included a visual inspection of the following areas: the embalming suite, the body store, the storage rooms and the dissecting room. Interviews were conducted with the DI (Professor of Experimental Neuroscience), the Person Designated (PD – Laboratory Manager), the Deputy Laboratory Manager, the Laboratory Technician and the Corporate Licence Holder Contact (CLHC; Chair – UCL HTA Governance Committee, Professor of Musculoskeletal Pathology). A documentation review and audit trails were also carried out. Details of the forward and reverse audits are provided below.

When bodies arrive at the establishment for embalming, details on the LAO documentation are recorded in the register, a book kept in the embalming facility. Details on the identity tags (attached to wrists and ankles) for two bodies and two prosections in the dissecting room were checked using each unique index number in the register and on the relevant computer records. All specimens were matched, including location. An audit was completed for two records in the register against electronic and consent records. One transcription error was found where the patient's age had been recorded incorrectly in the register. A review of consent documentation confirmed that the age was correctly recorded in electronic records.

Two museum specimens were audited against physical location and the electronic database (which was under development) and no anomalies were found.

### Inspection findings

The HTA found the DI and the (Corporate) LH (CLH) to be suitable in accordance with the requirements of the legislation.

### Compliance with HTA standards

#### 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.	There are no existing regular governance meetings which cover HTA issues for staff working under the licence.  <i>See also Advice items 1 and 2.</i>	<b>Minor</b>

### Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	Many of the UCL policies and procedures for human tissue (e.g. the SOP 'Adverse Event and Incident Reporting') are several years out of date. In partnership with the CLHC, the DI is advised to review the HTA page of the UCL website to ensure that the contents are fit for purpose:  <a href="http://www.ucl.ac.uk/slms/research/human-tissue-act/">http://www.ucl.ac.uk/slms/research/human-tissue-act/</a>
2.	GQ1	In other establishments, regular governance meetings have covered items such as: adverse incidents, changes to SOPs, audits and their findings, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). It is advised that these meetings should be at least quarterly, should be governed by an agenda, and minutes should be circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings.
3.	PFE1, PFE2	During the summer months the temperature in the embalming room can occasionally exceed 27°C. The DI is advised to assess the risk that such a rise in temperature may pose to staff, bodies, specimens and the embalming process.
4.	PFE3, PFE5	Steps have been taken to set up a Memorandum of Understanding (MoU) with Kings College London for

		contingency and continuation of service. The DI is advised to ensure that this MoU is agreed and signed within a reasonable timeframe.
5.	PFE5	The DI is advised to keep copies of all maintenance contracts associated with both the facility and the equipment in a central area. This will ensure that facility and equipment maintenance will come under the quality management system and will remind staff when maintenance visits are due.
6.	D2	The DI is advised to clarify within the SOP 'Disposal of a Prosection' whether, for relevant specimens, pacemakers should be removed or not.

### Concluding comments

At the last site visit inspection of the establishment, three items of advice were given. The DI had proactively implemented all of these items before this current site visit inspection.

During the site visit inspection of the establishment, several areas of good practice were noted. These were:

- To ensure that the dignity of the deceased is always upheld the DI has put a number of safeguards in place:
  - a review of the security of the premises, documented in an SOP
  - a registration system to monitor student attendance and also to record dissecting table cleanliness. The DI and other persons working under the licence are aware of who is in the establishment at any given time, students and staff are given restricted access on their swipe cards, students are always accompanied and are not permitted into the anatomy suite at set times during the day.
  - a local 'Anatomy Laboratory Protocol' reflecting the requirements of the HT Act and the HTA Code of Practice on Anatomical Examination. This is given as a hand-out (in the dissection manual) and as a presentation by the PD at the beginning of term.
  - a declaration to be signed by all relevant visitors, including demonstrators and research students, to confirm that they have read and understood the Protocol.
  - prominent signs relating to important aspects of the local Protocol
- There is a high awareness of the need for security and the premises are well secured with key and code locks, an alarm, and CCTV cameras. There are variable entry rights and there is a published list of key holders. Students are limited to a maximum of 140 at any one time to ensure that there is sufficient space for anatomical examination to be carried out safely and efficiently.
- The premises were found to be exceptionally clean, and staff emphasised the importance of the cleanliness in order that the museum specimens could be used to their full potential.
- There is regular monitoring of formaldehyde levels, ventilation, temperature and humidity.
- There is a detailed Quality Manual, incorporating all the features given as advice at

the last site visit inspection.

- The DI is developing a detailed records management system, incorporating Access software.
- There is a UCL-wide HTA governance committee, consisting of all DIs and PDs at UCL, which meets regularly to share information and experience. This facilitates learning and understanding of staff and is a forum for the discussion of good practices.
- There is strong managerial support for staff to receive training in areas of individual interest and to attend external meetings and conferences.
- All incineration of human tissue is witnessed by a member of staff who travels with the incinerator contractor.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to the Governance and Quality Systems, Premises, Facilities and Equipment, and Disposal standards.

The HTA requires that the DI addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfall identified during the inspection.

**Report sent to DI for factual accuracy: 20 October 2014**

**Report returned from DI: 19 November 2014**

**Final report issued: 22 November 2014**

#### **Completion of corrective and preventative actions (CAPA) plan**

**Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.**

**Date: 13 November 2015**

## Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment are shown in grey text.

Consent standards
<b>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</b>
<ul style="list-style-type: none"><li>• Consent forms comply with the HTA's Code of Practice</li><li>• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose</li><li>• 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</li></ul>
<b>C2 Information about the consent process is provided and in a variety of formats</b>
<ul style="list-style-type: none"><li>• Standard operating procedures (SOPs) detail the procedure for providing information on consent</li><li>• Independent interpreters are available when appropriate</li><li>• Information is available in suitable formats</li></ul>
<b>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent</b>
<ul style="list-style-type: none"><li>• Standard operating procedures (SOPs) detail the consent process</li><li>• Evidence of suitable training of staff involved in seeking consent</li><li>• Records demonstrate up-to-date staff training</li><li>• Competency is assessed and maintained</li></ul>
Governance and quality system standards
<b>GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process</b>
<ul style="list-style-type: none"><li>• Policies and procedures are in place, covering all licensable activities</li><li>• Appropriate risk management systems are in place</li><li>• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes</li><li>• Complaints system</li></ul>
<b>GQ2 There is a documented system of quality management and audit</b>
<ul style="list-style-type: none"><li>• A document control system, covering all documented policies and standard operating procedures (SOPs).</li><li>• Schedule of audits</li></ul>

<ul style="list-style-type: none"> <li>• Change control mechanisms for the implementation of new operational procedures</li> </ul>
<p><b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</b></p>
<ul style="list-style-type: none"> <li>• Qualifications of staff and training are recorded, records showing attendance at training</li> <li>• Orientation and induction programmes</li> <li>• Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training</li> <li>• Training and reference manuals</li> <li>• Staff appraisal / review records and personal development plans are in place</li> </ul>
<p><b>GQ4 There is a systematic and planned approach to the management of records</b></p>
<ul style="list-style-type: none"> <li>• Documented procedures for the creation, amendment, retention and destruction of records</li> <li>• Regular audit of record content to check for completeness, legibility and accuracy</li> <li>• Back-up / recovery facility in the event of loss of records</li> <li>• Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)</li> </ul>
<p><b>GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</b></p>
<ul style="list-style-type: none"> <li>• There is an identification system which assigns a unique code to each donation and to each of the products associated with it</li> <li>• 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</li> </ul>
<p><b>GQ6 There are systems to ensure that all adverse events are investigated promptly</b></p>
<ul style="list-style-type: none"> <li>• Corrective and preventive actions are taken where necessary and improvements in practice are made</li> <li>• System to receive and distribute national and local information (e.g. HTA communications)</li> </ul>
<p><b>GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</b></p>
<ul style="list-style-type: none"> <li>• Documented risk assessments for all practices and processes</li> <li>• Risk assessments are reviewed when appropriate</li> <li>• Staff can access risk assessments and are made aware of local hazards at training</li> </ul>

## 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.