Site visit inspection report on compliance with HTA minimum standards

Department of Physiology, Development and Neuroscience, University of Cambridge

HTA licensing number 12146

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.**

3 and 4 September 2013

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.

Although the HTA found that the Department of Physiology, Development and Neuroscience, University of Cambridge (the establishment) had met the majority of the HTA standards, two minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to audit and traceability. Advice has also been given relating to the GQS and Premises, Facilities and Equipment (PFE) 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 (DI), Licence Holder, 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 the Department of Physiology, Development and Neuroscience, University of Cambridge (the establishment). The establishment's licensing arrangements cover the Department of Physiology, Development and Neuroscience, University of Cambridge (the hub site) and the Surgical Skills Laboratory, Ipswich Hospital NHS Trust (the satellite site). Before the Human Tissue Act came into force, previous inspections of this establishment were carried out by HM Inspector of Anatomy; the last of these were in December 2004 (hub site) and September 2005 (satellite site). This was the first site visit HTA inspection of the establishment since it was issued an HTA licence in June 2007.

<u>The hub site</u>

The storage and anatomical examination of human cadavers is carried out at the hub. Approximately 50 donated cadavers are accepted for undergraduate and postgraduate courses each year. All consent procedures and consent information are provided to potential donors by the Bequeathal Office at the establishment. The establishment's consent form covers bequeathal of the body for anatomical examination, education, training and research.

The deceased are embalmed within the facility. There is an agreement between the establishment and a local 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, consented to be retained for longer than the originating body, will also

be cremated. Smaller body parts and prosections, consented to be retained for longer than the originating body, are sensitively disposed of by incineration at the local NHS Trust under an agreement between the establishment and the Trust.

Whole bodies and prosected material are used for teaching human anatomy to medical students in year 1 (cadaveric dissection) and year 2 (neuroanatomy prosection). Approximately 300 medical students and a smaller number of natural sciences students use the facility. The establishment organises revision sessions for clinical students and external courses for undergraduate and postgraduate medical training. Qualified surgeons, nurses, physiotherapists and anaesthetists also use the facility for professional training.

The dissecting room contains 48 dissecting tables (with six students allocated to each table) along with storage cabinets for prosected specimens. The adjacent 'annexe' contains five stations for demonstrating medical imaging, surface anatomy, patient interaction, osteology and clinical case studies, along with storage space for body parts, including wet neuroanatomical and foetal specimens and neuroanatomical slides (40 specimens in total). The osteology store is located in the balcony and in the preparation room areas and contains a secure collection of bones (approximately 200 specimens).

The site visit inspection of the hub included a visual inspection of the following areas: the embalming suite, the temporary body cold store, the prosection suites, the preparation room, the body store and body parts store, the dissecting room, the annexe and the osteology store. Interviews were conducted with the DI (Clinical Anatomist), the Persons Designated (PDs - Clinical Anatomist, Deputy Clinical Anatomist and Bequeathal Secretary) and the Principal Departmental Technician. A documentation review and audit trails were also carried out. Details of the hub forward and reverse audits are provided below. An audit trail was also performed of four temporal bones (two sets of matched right and left) which had been transferred to the satellite for a surgical training course (see below).

Details on the identity tags (attached to ears, thumbs, toes) for three cadavers in the body store and two cadavers in the temporary body store were checked against each unique index number in the relevant computer and hard copy records. All specimens were matched, including location. A similar reverse vertical audit was completed for three prosections in the body parts store. Each prosection was matched in the Parts Register to its location and its original cadaver, and matched to records of cremation for one cadaver. Additionally, a forward audit was performed, where two consent forms were used to track prosections. One prosection had been correctly disposed of and one was correctly located in the body parts store.

At the time of the inspection, the osteology collection was being catalogued (*see Advice item 5*).

<u>The satellite site</u>

The satellite at the Surgical Skills Laboratory, Ipswich Hospital stores a total of approximately 56 preserved temporal bones (28 right, 28 left) for use in regional and national Ear, Nose and Throat (ENT) training courses. Course numbers vary between 22 and 28 attendees. This material is returned to the hub for disposal on an annual basis. The site also stores approximately 25 preserved prosected specimens, which are kept in a -20°C freezer.

The site visit inspection of the satellite included a visual inspection of the surgical training area (a large open space with 12 workstations around the periphery and central CCTV link to the adjacent lecture theatre) and the store where the freezer was located. Interviews were conducted with the PD at the satellite (Consultant ENT Surgeon), the Surgical Skills Laboratory Manager, the Postgraduate Centre Manager and the Course Administrator. Details of the satellite forward and reverse audits are provided below.

Three prosected specimens were chosen from the freezer and matched to the unique

identifiers on the computerised records. One specimen had been incorrectly transcribed into the records (*see Advice item 1*). The two pairs of temporal bone specimens whose details had been given by the hub could not be located on the computer records and there was no indication that they had been returned to the hub.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. A change of DI took place soon after the inspection, on 2 October 2013.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	At the time of the inspection, there was no evidence that any audits had been completed. *See Advice item 4*.	**Minor**
GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The audit trail revealed discrepancies when material was being transferred between the hub and satellite site. *See Advice item 6*.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1, GQ4, PFE2, PFE3	Policies and SOPs have been created for a large range of activities and are included in the Quality Manual. The DI is advised to consider adding specific SOPs on the following: - Record creation, amendment, retention and destruction - Cleaning and decontamination of premises, storage facilities and equipment - Fridge and freezer temperature monitoring (including acceptable temperature ranges and actions to be taken when out of range).
2.	GQ1	The DI has initiated a Human Anatomy Teaching and Management Group (HATMG), which discusses all issues related to the licence. The DI is advised to consider how frequently this group should meet (for example, at least every three months) and who should attend (for example, the PDs from both the hub and satellite sites, and the Principal Departmental Technician).
3.	GQ1	The DI may wish to consider setting up meetings with other DIs

		working in the University or local NHS Trust to share information and experience with them and their PDs. This may help facilitate the learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
4.	Principally GQ2 but also relevant to standards GQ4, GQ5	The DI is advised to work with members of the team to divide the audit schedule into small increments, carried out by different team members. This should include procedural horizontal audits, which will help to ensure that SOPs accurately reflect the practices being carried out, and vertical audits of records and specimens on a scheduled basis, including traceability audits between hub and satellite. The results of all audit findings, and actions taken, should be formally recorded.
5.	GQ4	The DI is advised to continue and complete the cataloguing of the osteology collections.
6.	Principally GQ5 but also relevant to standards GQ4, PFE4	The DI is advised to set up a single register containing all specimen details at both hub and satellite. There are already databases and paper registers for cadavers, body parts and prosections at the hub, and prosections at the satellite. The DI is advised to consider whether these registers can be unified, perhaps with restricted access, to record the full traceability details of cadavers, body parts and prosections, from receipt to storage, cremation, burial or incineration. The DI is advised to consider creating a 'chain of custody' system for specimens transported between hub and satellite, confirming the dates when specimens have left and arrived at each site.
7.	GQ6	The SOP on adverse incidents incorrectly reflects licensable activities in the human application sector and the corresponding requirements for reporting serious adverse events and reactions (SAEARs) to the HTA in that sector. The DI is advised to amend the SOP accordingly.
8.	GQ6	The DI is advised to create an 'adverse incident log'. Examples of such events which could be reported could include: - Loss of dignity of the deceased (security breaches, interference with a body, unconsented photography of a body, accidental damage to a body) - Incorrect disposal - Body parts, cadaver, prosection loss - Incomplete records - Fridge/freezer warming or breakdown. The incident reporting system should ensure that follow up actions are identified and their completion is recorded.
9.	GQ7, PFE1, PFE3, PFE4	There are risk assessments for some, but not all, of the premises and practices. The DI is advised to expand the suite of risk assessments to include the following:

		- The surgical training area at the satellite - Storage in the temporary body store at the hub - Hub and satellite fridge and freezer breakdown out of hours, particularly over long periods such as a bank holiday weekend, including the identification of contingency storage facilities - Transportation between hub and satellite (potentially using a double bagging procedure). The DI is advised to consider extending the existing wireless temperature monitoring system to cover all fridges and freezers.
10.	PFE1	To facilitate effective cleaning, the DI is advised to replace the porous headrests on the embalming tables in the hub's prosection suites.
11.	PFE1	The DI is advised to ensure that visitor registers at both hub and satellite are completed at all times.
12.	PFE1	The DI is advised to ensure that all buckets at the satellite site containing prosected specimens are labelled 'Human Tissue' and have the appropriate Health and Safety warning signs.
13.	PFE5	The DI is advised to keep copies of all maintenance contracts in a central area at both the hub and satellite. These would include maintenance contracts for: premises ventilation, fridges, freezers and equipment (microscopes, drills, embalming equipment, band saw, hydraulic trolleys, embalming tables, hoists). This will ensure that facility and equipment maintenance will come under the quality management system and will remind staff when maintenance visits are due.

Concluding comments

During the inspection of the Department of Physiology, Development and Neuroscience, University of Cambridge, several areas of good practice were noted. These were:

- To ensure that the dignity of the deceased is always upheld the establishment has put a number of safeguards in place:
    - a registration system to monitor student and visitor attendance. The DI and other persons working under the licence are aware of who is in the establishment at any given time, staff are given restricted access on their swipe cards and students are only admitted into the anatomy suite at set times during the day.
    - a local code of conduct reflecting the requirements of the HT Act and the HTA Code of Practice on Anatomical Examination (Code 4). This is given as a handout (in the dissection manual) and as a presentation by the DI at the beginning of each term.
- There is a detailed process for seeking, obtaining and recording consent, including a consent policy, SOP, and checklists to record all details of the donation (including acceptance criteria) and its tracking to burial or cremation. Copies of all forms are held

securely in the Bequeathal Secretary's office.

- At the hub site, there is a high awareness of the need for security and the premises are well secured with intruder passive infrared motion sensors (PIRS), key locks and external CCTV cameras. There are variable entry rights to swipe card access and there is a published list of key holders. Students' numbers are limited to ensure that there is sufficient space for anatomical examination to be carried out safely and efficiently.

- At the satellite there is also a high awareness of the need for security and the premises are similarly well secured with an intruder PIRS system, key locks, barred windows and CCTV cameras.

Two minor shortfalls have been identified as a result of the site visit inspection. In addition, the HTA has given advice to the DI in several areas, including governance and quality systems and premises facilities and equipment.

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 shortfalls identified during the inspection.

Report sent to establishment for factual accuracy: 2 October 2013

Report returned from DI: 14 October 2013

Final report issued: 6 November 2013

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 April 2017

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.

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 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.