Site visit inspection report on compliance with HTA minimum standards

Gordon Museum

HTA licensing number 12373

Licensed under the Human Tissue Act 2004 for 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; and**
- **use, for the purpose of public display, of the body of a deceased person or relevant material which has come from the body of a deceased person**

13 October 2015

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.

The Gordon Museum (the establishment) was found to have met all HTA standards. Since the previous inspection in August 2010, the museum had refurbished a part of the premises and introduced CCTV monitoring of all areas within the museum.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The Gordon museum opened in 1905 and is the largest teaching medical museum in the UK. Kings College, University of London, is the HTA licence holder and the corporate licence holder contact is the Director of Research Management and Innovation. The Designated Individual is the Curator of the museum.

The museum is not open to the general public and so its current activity relates to the storage of relevant material for use for education and training. The museum would like to open a section for the public sometime in the future, but plans have not yet been formalised (see advice items 1 and 3).

This was the second routine HTA inspection; the previous inspection was undertaken in August 2010. It included interviews with the Designated Individual, the corporate licence holder contact and the Departmental Secretary. The HTA team visited the main museum galleries, preparation room and the workshop.

The museum is used by professionals and students in the areas of biological sciences, medicine, dentistry, physiotherapy and forensic science. Visitors include healthcare professionals from all over the world. Access by health care professionals and students who are not associated with Kings College London, is by appointment; background and identification checks are undertaken by staff before they are allowed access.

The museum has three full time members of staff – the Curator (DI), Administrator and Technical Assistant. In addition to taking care of specimens, they man the entrance to the museum, check the identity of visitors and monitor the images displayed by CCTV cameras. Deputy medical curators provide advice to the DI as required.

The museum is housed within the Hodgkin building and is under 24-hour security cover. There are signs warning visitors that CCTV cameras continuously record images which are stored on the security system. All specimens are electronically tagged and an alarm will sound if specimens are taken outside the display area of the museum. The alarm system was checked during the inspection by randomly taking two pots outside the door of the museum; it operated as expected.

There is signage throughout the museum to inform visitors that they are forbidden to take photographs or record moving images. Fire extinguishers are placed in several areas around the museum; they are checked on a regular basis.

The museum has four bays, each consisting of three floors set around a central stairwell. The ground floor has study areas and lecture theatres. Specimens are arranged along the walls of the bays. The specimens are arranged by biological systems and topics. Brief descriptions are displayed near the specimens and reference books containing more detailed information are placed near groups of specimens.

As well as collections of prosthetics, surgical instruments, wax models, paintings and artwork, the museum contains around 8,000 specimens ranging from whole bodies to skeletons, organs, soft tissues, skin, bones and pathological specimens. The oldest specimen dates from 1608. The majority of the specimens are ‘existing holdings’ in that they were part of the museum’s collection before September 2006, when the Human Tissue Act 2004 came into force.

Museum staff are not involved in seeking consent, but ensure that appropriate and valid consent is in place for education and training and/or public display before new specimens are received into the collection. All new specimens are allocated a museum Daybook number. The date of acquisition, nature of the specimen, donor details, pathology of the specimen and other identification details (such as hospital number, post mortem number and details of transport) are recorded in the Daybook. The Daybook recording system has been in place since July 1891.The identification system used by the museum has evolved over the past 124 years. The museum keeps a record of the changes to the identification numbers made as each system came into use, so that individual specimens can be traced from acquisition to the current identification system. The museum also uses a printed index and an electronic database.

The museum has a workshop and a preparation room where potting and repotting of specimens takes place. Specimens such as organs and tissues are received packaged in formaldehyde and are trimmed or dissected before they are potted. Soft tissue specimens are displayed in bespoke plexiglass pots, which are made in the museum workshop. Deputy Medical Curators, or other professionals who advise the museum, write up details of interest such as the pathological diagnosis and an anonymised description of the donors which are filed in the books placed near the specimens.

The workshop and preparation rooms contain portable fume cupboards, which are under annual maintenance contracts; ventilation systems are in place to minimise staff exposure to formaldehyde. Dedicated cabinets are in use to store flammable and non-flammable liquids, and health and safety assessments are undertaken regularly. The preparation room also contains a downdraft table used by staff when repotting specimens. The staff induction manual emphasises the importance of health and safety as well as the care of human remains. Contract staff, who have received induction and training, are responsible for cleaning the museum; cleaning is recorded.

The Gordon museum does not arrange transportation of specimens; any specimens for the museum are sent to the mortuary at Guy's and St Thomas' NHS Foundation Trust (HTA licence 12243) and personally collected by museum staff. Very occasionally, specimens are provided to teaching staff or to researchers at Kings College who take them away for teaching purposes or scanning, which takes place in a neighbouring building. The specimens are returned by the end of the day (see advice item 4).

Staff undertake monthly documented traceability audits of specimens in order to check their location and condition. The specimens are re-potted as required. There is a system in place for quarterly documented external traceability audits undertaken by staff who work under the Anatomy Licence held by Kings College London (Licence no: 12123).

Museum staff have close links and provide advice and re-potting services to the Old Operating Theatre Museum and Herb Garret which is located nearby. The Old Operating Theatre Museum displays twenty human specimens from donors who died more than 100 years ago; these specimens fall outside the consent and licensing requirements of the Human Tissue Act 2004.

The HTA carried out a document review of policies, procedures and governance documentation. These included: the Governance Manual and Index and SOPs which cover visitor access to the museum, the care of specimens, preparation of potting solutions, temporary movement of specimens to adjacent parts of the campus and disposal of tissue or specimens. Audit reports, risk assessments, records of cleaning, equipment maintenance, meeting minutes of Kings College HTA Governance group, forms relating to reporting adverse events were also reviewed.

Several audit trails were undertaken. The establishment has a comprehensive location map of all exhibits; five specimens randomly selected from this plan were traced from their display location in the museum and museum numbers, through to the museum Daybook. Records relating to specimens acquired after the previous HTA inspection in 2010 from donors who died after 2010 were reviewed; two of the specimens were located in the preparation room and will be placed in the museum in due course. The accompanying consent documentation did not specifically state that they could be used for public display and the HTA was assured that they would not be put on display to the public. There were no discrepancies.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to document the nature of consent for specimens received from deceased donors who died after September 2006, in order to distinguish donors who have given appropriate and valid consent for the specimens to be used for public display and those whose consent only relates to use for other scheduled purposes such as education and training or research. Specific requirements for consent for public display are set out in the HT Act 2004; in cases of any doubt, the DI is advised to seek legal advice.
2.	GQ1	The DI is advised to formalise contingency arrangements for the museum in order to clarify the roles of responsibilities of staff when dealing with emergencies out of hours.
3.	GQ6	The DI is advised to extend the range of risk assessments to cover public display in the event that the Gordon Museum takes forward plans for a gallery which will be open to the public. The risk assessments should consider risks relating to a lack of appropriate and valid consent and risks of theft, vandalism and damage.
4.	PFE3	The establishment has an SOP which covers the temporary movement of specimens. The DI is advised to strengthen the procedure by using a log book to record details of specimens being moved, which would help maintain traceability.
5.	D1	Although the establishment does not often dispose of tissues, an SOP is in place which covers disposal of specimens and tissues. The DI is advised to ensure that any sensitive material is identified and disposed of appropriately, in line with the HTA's code of practice. In addition, tissues from the deceased must be bagged separately before disposal.

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Concluding comments

The museum contains specimens of important historic and educational value. It is used by a wide range of students and professionals. There is good communication between staff at the establishment, who work well together, and staff turnover is low. The establishment is committed to continuous improvement. Since the previous inspection, security of the premises has been improved by installing CCTV, which is continuously monitored by staff during opening hours.

There are robust systems in place to ensure traceability. There are excellent links with staff who work under the Anatomy licence held by Kings College, London, who undertake external audits each quarter. The DI attends regular HTA Governance Group meetings where DIs of all HTA licences held by Kings College, London, meet to discuss issues relating to human tissue governance and share good practice.

There are a number of areas of practice that require improvement and the HTA has given advice to the Designated Individual with respect to documenting the nature of consent in place for specimens acquired since the HT Act came into force; formalizing contingency arrangements; logging temporary movement of specimens; strengthening the procedures for disposal of specimens and tissue samples from the deceased, and undertaking additional risk

assessments in the event that the museum takes forward plans to open a section of the museum to the public.

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

Report sent to DI for factual accuracy: 6 November 2015

Report returned from DI: 9 December 2015

Final report issued: 10 December 2015

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 Codes of Practice • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice

Governance and quality system standards
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, governing the storage and public display of bodies and relevant material • There is a system of risk management in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • There is a complaints system in place
GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Qualifications of staff and training is recorded • There are orientation and induction programmes for new staff • There is a documented training programme (e.g. health and safety, fire, risk management, infection control), including developmental training
GQ3 There is a systematic and planned approach to the management of records
• There are documented procedures for the creation, amendment, retention and destruction of records • There is regular audit of record content to check for completeness, legibility and accuracy • There is a back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ4 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 specimen, and to each of the products associated with it
GQ5 There are systems to ensure that all adverse events are investigated promptly
• There is a system for reporting adverse events • Corrective and preventive actions are taken where necessary and improvements in practice are made
GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• There are 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 licensed activities • There are policies in place to review and maintain the safety of staff, students and visitors • Where appropriate, policies are in place to ensure that the premises are of a standard that ensures the dignity of the deceased • 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 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination
• There are documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • There is a contingency plan for equipment failure
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells.
• Bodies and relevant material are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Critical storage conditions are monitored and recorded

• There are systems to deal with emergencies out of hours
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
• A system is in place to ensure that traceability of specimens is maintained during transport • Records of transportation and delivery are maintained • Records are kept of any agreements with courier or transport companies

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• There is a documented disposal policy • There is compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• There is a system for tracking the disposal of relevant material, including recording 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.