Site visit inspection report on performance against HTA quality standards
Imperial War Museum
HTA licensing number 12550

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**

26 June 2013

Executive Summary

A site visit inspection of the Imperial War Museum (the establishment) was carried out by the HTA on 26 June 2013.

The establishment was found to have met all applicable HTA standards.

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.

Particular examples of strengths and good practices are included in the concluding comments section of this 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 Designated Individual are set down in Paragraph 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 Imperial War Museum London (the establishment). The establishment holds a varied collection of records, exhibits and specimens associated with war and conflict dating from the First World War to the present day. The collection focuses on Britain, its former Empire and Commonwealth. The establishment uses its collection in galleries, displays and events which depict images, experiences and the impact of war and conflict.

As part of its collection, the establishment has a small number of specimens that are human remains or are believed to be human remains. As they were acquired or donated prior to 1 September 2006, these specimens fall outside the consent provisions of the Human Tissue Act 2004 (HT Act). The establishment has closed its collection of specimens of human remains and the current policy precludes acquisition of further human remains. The scope of the inspection was therefore limited to the licensable activities relating to the small collection of specimens, and included the public areas of the establishment and the storage area which currently houses the collection of relevant material.

The museum is currently closed to members of the public whilst extensive building works take place to create new galleries, including a remodelled central atrium, which will house a new

exhibition to coincide with the First World War Centenary. There are no plans to display specimens of human origin in the planned exhibitions or any future exhibitions.

This was the first HTA site visit inspection of the establishment. The timetable for inspection was developed with due consideration of the establishment's self-assessment exercise at initial licence application and under HTA Directions 002/2011, and pre-inspection discussion with the Designated Individual (DI). The inspection comprised a visual inspection of the museum, the museum's storage areas and the security control room. In addition, interviews were held with members of staff involved in licensable activities, and documents and related databases associated with the establishment's governance and quality systems were reviewed to verify compliance with HTA standards and related codes of practice. An aspect of this review included a traceability audit whereby a random selection of specimens were tracked and traced using the proprietary collections management system in order to verify that the stipulated location and status matched the specimens' actual location and status. All items were accounted for and found to be within the areas recorded in the database.

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

Advice

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

No.	Standard	Advice
1.	GQ3	The DI is advised to introduce a system and procedure to document periodic audits of the location and condition of specimens when members of staff carry out checks on storage areas.
2.	GQ6 & PFE1	The DI is advised to formally document the risk assessment of premises that encompass the storage of relevant material. In particular, consideration should be given to: • the routing of services to minimise risk to specimens during any structural changes; • the storage of collections off the floor to minimise water damage in the event of any flooding; • the installation of sensors / detectors to provide early warning of hazards that pose a risk to the specimens; • the type of packing material used to protect the specimens whilst in storage.

Concluding comments

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 HTA is satisfied that the establishment is suitable to be licensed under the Human Tissue Act 2004 for the storage and public display of relevant material which has come from the body of a deceased person.

The Designated Individual (DI) has a good knowledge of applicable HTA standards and codes of practice. Members of the team responsible for licensable activities are aware of regulatory requirements and work closely as a team to assure compliance.

The establishment has a sound governance structure supported by policies, systems and procedures that reflect a conscientious and sensitive approach to licensable activities. The DI is closely involved in the oversight and management of activities and has good links into the various board level meetings that consider matters of governance.

There is good communication between members of staff working in different departments such as collection management and conservation. Documents relating to governance undergo periodic review and are under a system of change control. The DI is involved in the induction programme for new members of staff and has developed a useful presentation which includes the establishment's licenses and the responsibilities and obligations of staff involved in licensable activities.

The establishment has implemented additional procedures to safeguard and maintain the integrity of specimens during the on-going refurbishment of the premises; for example, the additional measure to seal the doors of specimen storage rooms that have been considered at risk of exposure to dust during the building works.

The 2005 / 2006 cataloguing project has resulted in detailed and comprehensive records of specimens that are being held on the proprietary computer system. The catalogue and associated systems were demonstrated to provide ready access to specimens with minimum disruption or impact on other packaged specimens.

The 2007 repacking project resulted in a review of packing components to ensure that the establishment only uses inert contact materials in order to minimise the risk of deterioration to specimens.

Facilities are well monitored and controlled. There are sound security measures in place with continuous oversight of a number of security controls that are managed and monitored from a central security control room. The environments in which collections are exhibited and stored are closely controlled by a building management system which has a sentinel environment control system monitoring operation within closely defined specifications.

Two items of advice have been offered to the DI in the spirit of continuous improvement, with respect to documenting risk assessments and audits.

Report sent to DI for factual accuracy: **9 July 2013**
Report returned from DI: **12 July 2013**
Final report issued: **15 July 2013**

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 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
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 • Agreements with third parties who provide material for public display contain information about consent requirements
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 • There is 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 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 in place 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 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.