Site visit inspection report on compliance with HTA minimum standards

The British Museum

HTA licensing number 12526

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**

08 and 09 October 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.

The British Museum (the establishment) was found to have met all HTA 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, 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 (HT Act). 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 British Museum, which houses a collection of world art and artefacts and includes one of the largest ethnographic collections worldwide.

As part of a collection of over 8 million objects, the establishment has approximately 4,000 specimens that are, or are believed to be, human remains. The majority of these are outside the scope of the HT Act, as over 100 years have elapsed since the date of the person's death.

The establishment has ten curatorial and research departments, two of which hold between them 182 items containing relevant material under the HT Act. These were all acquired or donated prior to 1 September 2006; they are therefore existing holdings and fall outside the consent provisions of the Human Tissue Act 2004 (HT Act).

For the purposes of HTA licensing, the establishment comprises a hub facility at the British Museum and a satellite facility at Frank's House, which is an outstation site of the establishment. A new World Exhibition and Conservation Centre (WECC) is currently under construction in the north west corner of the main British Museum site. This is due to open in 2014 and will provide specialist facilities for conservation, scientific research and collection management. Once building work is completed, the establishment is intending to relocate all of its human remains from the satellite site into dedicated storage within the WECC. Plans for this move were reviewed during the course of the inspection.

The establishment currently has three items of human origin on public display, that are within the scope of the HT Act. These are located within two separate galleries at the hub site. All other relevant material that is held under licence by the establishment is located within secure storage areas at the hub and satellite sites. These areas are overseen by Senior Museum Assistants. Written permission is required from the DI in order to access any item in the collection held under the establishment's HTA licence.

This was the first HTA site visit inspection of the British Museum and included a visual inspection of museum galleries and storage areas, as well as the storage facilities at the satellite site. Interviews were held with staff involved in licensable activities and documents pertaining to the establishment's activities were reviewed in order to verify compliance with HTA standards and codes of practice.

An audit trail exercise was conducted, whereby seven specimens were traced using the establishment's digital records system to verify that each specimen's status and location were recorded correctly. These specimens were selected at random from each collection storage area that was visited. The same exercise was also conducted for each of the three exhibits currently on public display. A further stored specimen was reconciled with an entry in the establishment's original hand-written acquisition log, which also matched an entry in the digital records system.

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.		The DI is advised to formalise the responsibilities of those involved in the move of human remains into the WECC. One way of doing this would be to increase the number of named Persons Designated that work under the HTA licence.
2.		The DI is advised to display a copy of the HTA licence in areas where relevant material is stored.
3.	GQ1	The DI is advised to expand the existing programme of audits to include planned audits of compliance with HTA standards, as well as an audit of human remains held in the collection. This human remains audit could cover material held under HTA licence and material that is known to be over 100 years old.
4.	GQ2	The DI is advised to incorporate the document 'Guidance on how BM operates under terms of HTA licence' into staff training material. This information could then be circulated as part of any induction programmes held by the establishment.
5.	GQ3	The DI is advised to consider including version control in policy and procedural documentation to help ensure that staff refer to the most recent versions of all documents.
6.	GQ6	The DI is advised to conduct a risk assessment, which specifically considers visitors and contractors working in the stores areas.

Concluding comments

The establishment was found to have met all applicable HTA standards. There were many strengths and areas of good practice observed throughout the inspection. Some of these are documented below.

All human remains in the collection are treated with the same high standards of care, dignity, respect and cultural sensitivity, regardless of their age. This means that any material held under the HTA licence benefits from the broader systems and processes developed by the establishment for the curation, conservation, loan and security of all of the items held within its collection.

The establishment assigns a unique registry number to each item held, which includes the date that the item was accepted into the collection. For human remains of similar provenance, this provides a straightforward method of distinguishing between material held under licence and material known to be over 100 years old.

Staff members at the establishment are mindful of the museum's reputation and of the risks that are associated with storing human remains. A document has been written to provide guidance to staff that work with human remains and HTA-specific activity is clearly highlighted. In all matters concerning human remains that are, or may be, less than 100 years old, the DI is contacted before any actions are taken.

The establishment has a broad audit programme in place and has demonstrated through the results of this, that risk control and governance are successfully managed. The safety and security of all items within the museum are well considered and regular stores surveys are conducted to evaluate any risks to the collection.

The establishment is using the move into the new WECC as an opportunity to undertake a comprehensive review of the material held within its storage archives.

The build of this new centre has also allowed the establishment to drive up its own standards for storage and conservation. Taking into consideration the methods used within the current facilities, the new purpose-built centre has incorporated: preventative measures for pest ingress and monitoring; building management and environmental control systems; use of inert materials for storage and display of collections; and purpose built drawers and racking which allow access to be secured and controlled.

In the spirit of continuous improvement, the HTA has offered the DI a number of items of advice.

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

Report sent to DI for factual accuracy: 06 November 2013

Report returned from DI: 20 November 2013

Final report issued: 25 November 2013

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
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 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.