Site visit inspection report on compliance with HTA minimum standards

UCL Public and Cultural Engagement

HTA licensing number 12620

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**

2 September and 7 October 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 Public and Cultural Engagement (the establishment) had met the majority of the HTA standards, five minor shortfalls were found with regard to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. The shortfalls were in relation to standard operating procedures, governance meetings, audits, risk assessments and transportation procedures. Advice has also been given relating to the GQS 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 University College London (UCL) Department of Public and Cultural Engagement (PACE; the establishment). In the public display sector, it is HTA policy to undertake a full site visit inspection before material of human origin is put on display, to ensure that the HTA's standards are being met.

PACE is a Department within UCL Professional Services. It is home to the Units of: UCL Museums and Collections; UCL Public Engagement; and the Bloomsbury Theatre. It is the UCL Museums and Collections Unit which is licensed for public display under the HT Act.

The establishment applied for the licence in May 2014 in order to support teaching, research and public engagement at UCL in a number of ways: by setting up static exhibitions and displays; by extending the teaching use of the collections to non-medical students at UCL; by contributing specimens to researcher-led public exhibitions; by supporting medical staff at UCL to run public events such as health awareness community workshops and lectures; and, by supporting UCL's 'outreach and widening participation' initiatives to promote pathology and the study of medicine to aspiring students. The ultimate aim will be to establish a medical museum at UCL.

PACE manages four Arts Council England-accredited museums and 12 Teaching and Research Collections. The four accredited museums are: UCL Petrie Museum; UCL Art Museum; UCL Geology Collection; and, UCL Grant Museum. There is also the Octagon

Gallery, various Teaching and Research Collections - UCL Archaeology, UCL Anthropology, Galton, Science, and Pathology Collections – and teaching rooms around the campus such as seminar spaces and lecture theatres where teaching and public engagement take place. It is envisaged that several of these museums, collections and spaces will be used for the future public display of human material.

It is the Pathology Collection which contains approximately 8,000 specimens of human material from both living and deceased donors which will be used for public display. This collection is currently housed at three sites: The Whittington Hospital (where approximately 40 preserved specimens are stored under HTA Post Mortem (PM) licence 12099); The Royal Free Hospital (where 6,950 preserved specimens, 100 blocks and slides, and 360 bones are stored under PM licence 12013) and University College Hospital (where 510 preserved specimens and 100 bones are stored under PM licence 12054). The Royal Free Hospital collection is the largest and is made up of several historic teaching collections of fetal, surgical, post-mortem, paediatric and gynaecological specimens. All the specimens in the Pathology Collection are existing holdings and several are more than 100 years old. There are no plans for collecting further specimens. The Consent Standards, C1-C3, are therefore not applicable in this case.

The Pathology Collection is currently being assessed, re-preserved and catalogued. Each specimen is being photographed and catalogued in paper and digital records and will be given a storage location. Disposal of specimens rarely takes place.

The site visit inspection included a visual inspection of areas where public display of human material will take place (UCL Petrie Museum, UCL Art Museum , UCL Grant Museum, the Octagon Gallery and UCL Geology), as well as the largest current storage facility (at the Royal Free Hospital) and the Bloomsbury and Royal Free Conservation Laboratories. The Royal Free Hospital visual inspection was carried out on a separate date. Meetings were held with the DI (Head of Collections Management), the (Corporate) LH Contact (Head of Museums and Collections), the Person Designated (Curator - UCL Teaching and Research Collections: Biomedical and Galton) and the Conservator. Documentation reviews and records audits were carried out. Two specimens were selected at random from each of three separate paper catalogues and records compared with the digital register (which is backed up). All specimen details were correctly transcribed. The records for the loan and return of a batch of 30 specimens were also examined. There were some anomalies (*see Standard GQ3, below*).

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 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process.	There are no Standard Operating Procedures (SOPs) to cover the following activities: • specimen preservation and monitoring (including the checking of preservative levels of exhibits). • control of environmental conditions and housing. • spillage cleaning and decontamination. *See Advice item 1.*	**Minor**
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process.	There is no regular forum where staff working under the licence can discuss HTA issues. *See Advice item 2*.	**Minor**
GQ3 There is a systematic and planned approach to the management of records.	There is currently no regular audit of record content to check for completeness, legibility and accuracy. During the inspection it was found that the records for the loan and return of a batch of 30 specimens had discrepancies. The standard loan condition document stated that the maximum term for loans was one year but there was evidence that around a third of the batch were still out on loan after three years. The loan documents were also not complete and were missing the signatures of both staff at the establishment and staff at the organisation which had received the loan. *See Advice item 4*.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	There are risk assessments relating to Control of Substances Hazardous to Health (COSHH) in relation to laboratory procedures. There are no risk assessments for activities relating directly to human material, such as: • specimen receipt • storage • transport • display • loan • disposal (of the wrong sample). *See also Advice item 7*.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.	It is envisaged that there will be frequent transport of specimens from offsite storage to the establishment during public display events. The establishment has a good idea of how this will be done in practice, but there is not yet a formal SOP for transportation which covers: • authorised personnel who can accompany transportation (e.g. staff, porters) • authorised personnel in the Curator's absence • transportation conditions • records of transportation and delivery • agreements with professional carriers (e.g. St John Ambulance).	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	There is inconsistency in the current format of standard operating procedures (SOPs). The DI is advised to consider the inclusion of the following features to each document to create a more robust system and to ensure that the most up-to-date documents are being used:

		• Document control information, such as a revision history and version number • 'Effective from' date • Review date (at least every three years) • Pagination • The names of both the author and the reviewer who has authorised the content of the document (the reviewer should have knowledge of the relevant procedure/process but need not be more senior than the author).
2.	GQ1	In other establishments, such HTA 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 governed by an agenda and that minutes are recorded and 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. The DI may wish to consider incorporating the HTA forum as part of the Collections Advisory Group (CAG) or UCL Museums, Heritage, and Cultural Property Committee (see below).
3.	GQ2	The DI may wish to consider using the HTA 'Code of Practice on Public Display (Code 7)' as part of its training programme.
4.	GQ3	The DI is advised to formalise a schedule of audits carried out by different members of staff. It could include process audits to ensure that SOPs accurately reflect current practices, vertical human specimen traceability audits, from records of receipt to storage, loan or disposal, and horizontal audits. The DI may also wish to consider implementing a regular audit against HTA standards. The results of all audit findings, and actions taken, should be formally recorded to ensure continuing improvement of processes and practices.
5.	GQ3	The DI is advised to ensure that the paper copies of loan documents are scanned to ensure that they can be permanently retained. The DI is also advised to amend the loan form to include a box to record date and signature for return of specimens.
6.	GQ5	There is no system for capturing adverse events relating to human specimens (e.g. unexpected environmental changes, specimen loss, inappropriate disposal, incorrect documentation). The DI is advised to keep a central log of all adverse events relating to human specimens. The results of actions taken (root cause analysis and corrective and preventative actions) should be formally recorded.
7.	GQ6	Once created, the DI should ensure that all risk assessments are reviewed regularly, that staff can access them and that familiarity with

		them is incorporated into the staff training programme.
8.	D2	The DI is advised to ensure that the date of disposal of each specimen is recorded and that the method of disposal is included in the relevant SOP, taking into account the nature of each specimen.

Concluding comments

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

- Management and staff are committed to making better use of this valuable resource of human tissue. The establishment has shown its commitment by investing in two conservation laboratories and by securing the Royal Free storage area.
- There are good lines of communication for: creating policies for the collections; for advising and making recommendations in the event of proposed disposal (by sale, gift, exchange or destruction); and, for making decisions on loan requests. These involve the CAG, the UCL Museums, Heritage, and Cultural Property Committee, the UCL Museums Senior Management Group and UCL Council.
- External training is encouraged. The Museums and Collections staff benefit from specialist training, e.g. wet specimen conservation and object handling and packing courses.
- A consultant histopathologist at the Royal Free Hospital has provided a full diagnosis on all 500 specimens of the Whittington collection. These have now been re-preserved and catalogued. Staff now intend to work with the histopathologist to extend this to all the collections.
- The establishment works within the Museums Association Code of Ethics for Museums and uses the Museums Association Disposal Toolkit.
- UCL already has Arts Council England accreditation for four of its museums. It aims to obtain Arts Council England accreditation for this current collection in due course.

There are a number of areas of practice that require improvement, including five minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality Systems 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 5 November 2014

Report returned from DI: 18 November 2014

Final report issued: 9 December 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: 20 October 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 are highlighted as grey text.

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.