Inspection report on compliance with HTA licensing standards
Inspection dates: **10 December (remote) and 11 December (site visit) 2024**

City, University of London T/A City St George's University of London
12330

Licensed under the Human Tissue Act 2004

Licensed activities

Area	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	Storage of an anatomical specimen
St George's, University of London	Licensed	Licensed	Licensed	Licensed

Summary of inspection findings

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

Although City, University of London T/A City St George's University of London ("the establishment") was found to have met most of the HTA standards, two minor shortfalls were identified against Governance and quality systems standards and Premises, facilities and equipment standards, in relation to; document control and preservation of specimens.

Compliance with HTA standards

Minor shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
b) There is a document control system.	The establishment did not have a robust system for managing document control for standard operating procedures (SOPs). In some instances, the version history was different on the document control spreadsheet compared with the SOP. There was also a lack of document history where old SOPs had been archived and new SOPs created. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	During the visual inspection, it was noted that some specimens in the Pathology Museum were not sufficiently submerged in preservative fluid, posing a risk to the physical integrity and long-term preservation of those specimens.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to include suitable linkage to the corrective and preventative action plan process to SOPs relating to adverse events and audits. This should help to strengthen these procedures by ensuring that a clear and consistent process for managing identified actions is followed.
2.	GQ1(a)	Although the establishment has a comprehensive suite of SOPs, some of them contain similar information. The DI should consider undertaking a review of the full suite of SOPs, to ascertain whether further streamlining and consolidation may help staff to access the relevant documented procedure more easily and efficiently.
3.	GQ1(b)	The document control system records the revision history of SOPs and the next review dates. The DI should also consider adding the next review date to individual SOPs to serve as a reminder to staff for when the next review is due.

4.	GQ3(b)	The establishment trains all new staff who will be working in the anatomy laboratory. Although the competency of staff is assessed, this has not been formalised. The DI is advised to formalise the assessment and documentation of staff competency to evidence when a staff member has reached expected training targets.
5.	T1(b)	During a traceability audit in the Pathology Museum, it was discovered that a specimen labelled as 'Large Intestine' was, in fact, a specimen of small intestine. The DI is advise to consider how the Pathology Museum's Person Designated (PD) should carry out regular audits of the specimen inventory to ensure accurate labeling and prevent similar discrepancies in the future.
6.	PFE2(c)	The establishment carries out a quarterly check of electronic temperature monitoring versus manual temperature monitoring to ensure that there are no differences between the two. The DI is advised to consider documenting that this check is carried out to evidence that it has taken place and provide ongoing assurance through an audit trail.

Background

City, University of London T/A City St George's University of London ("the establishment") provides training for students across a number of allied health professions. The establishment also offers students access and use of the Pathology Museum which stores potted specimens, most of which are over 100 years old. At the time of the inspection, the establishment was not storing whole bodies with human tissue activities limited to use of prosections, plastinated specimens and bones.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

Of the 47 HTA standards, 39 were assessed (standards published 3 April 2017). Standards C1(a),(b),(d),(e) and (f) and C2(a),(b) and (c) were not applicable as staff at the establishment does not seek consent directly.

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, temperature monitoring data, maintenance/service records and incident reports.

Visual inspection

A visual inspection of the premises where human material is stored and used was undertaken during the site visit component of the inspection.

Audits

A number of specimen traceability audits were performed during the visual inspection. These are described below.

Prosections

Due to ongoing ventilation issues, the inspection team did not perform a physical audit of the prosections themselves but worked with the establishment to ensure they were audited.

The inspection team randomly identified seven bodies that had been donated previously and where prosections had been retained. For each body, the consent form was reviewed to demonstrate that appropriate consent for storage of the prosection was in place. A visual check of the fridge map by the inspection team also confirmed the storage location of each prosection. The technicians removed the prosections identified from seven bodies as part of the traceability audit and photographed these against the physical fridge location. The inspection team were provided with these images to confirm the location of each prosection. Appropriate consent was in place for all specimens and no discrepancies were identified. A further audit two prosections that had been received under a loan arrangement from another licensed establishment was undertaken. This material had been incorporated permanently into the establishment's collection. Appropriate consent was in place for the specimens and no discrepancies identified.

A records audit was undertaken of prosections removed and transferred under a loan arrangement to another establishment. The loan agreement was reviewed and no discrepancies identified.

Plastinated specimens

The traceability of nine plastinated body parts was reviewed by examining the consent documentation for each, confirming their storage location, and verifying the parts retained. All relevant records were in order, and no discrepancies were identified.

Pathology Museum

During the audit of four potted samples in the Pathology Museum, a minor discrepancy was identified where a specimen of the small intestine was labelled as the large intestine (see *Advice*, item 5)**.**

Fresh Frozen

A traceability audit of six bodies parts imported from outside of the UK was undertaken by reviewing the establishment's inventory records and agreement with the supplier. The agreement stipulated that consent was in place and no discrepancies identified.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Corporate Licence Holder contact (CLHc), Interim Executive Dean, Pathology Museum Person Designated (PD) and Teaching Prosector.

Report sent to DI for factual accuracy: 10 January 2025

Report returned from DI: 27 January 2025

Final report issued: 31 January 2025

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: 10 July 2025

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next inspection.

   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 the final inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.