Inspection report on compliance with HTA licensing standards
Inspection date(s): **26 March 2025**

Brunel University London

HTA licensing number 12726

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
Brunel University London	Licensed	Not 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 the HTA found that Brunel University London ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against Governance and quality system standards. These related to governance meetings and risk assessments for licensable activities.

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.

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		
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	Since the Human Tissue Governance Group was disbanded, matters relating to HTA-licensed activities are not discussed at regular formalised governance meetings involving establishment staff.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice	Risk assessments do not cover risks relating to the receipt, storage and use of specimens and focus predominantly on risks to individuals and risks to security.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Images of specimens are taken for cataloguing purposes, condition monitoring and student assessment. The process for photography is not documented in any of the establishment's SOPs. The DI is advised to include procedures in relevant documentation to ensure that suitable practices are taking place. Aspects to consider and cover include consent requirements (if applicable), the dignity of the deceased and an assurance that systems are in place to prevent the inappropriate use of images.
2.	GQ1(a)	There is a declaration on each of the establishment's SOPs to document that staff have read and acknowledge understanding of the content. The declaration is only completed once. The DI is advised to have staff sign for each version of the document so there is evidence of an understanding of the most up-to-date procedure.
3.	GQ1(a)	The 'Disposal of Human Tissue' SOP-13 has an error in the document control where the revision date has been updated but the 'next review date' has not been and still states 2024. The DI is advised to correct this date.
4.	GQ1(b)	Documents are reviewed annually but the document history table is only completed when documents are modified. The DI is advised to complete this table after every annual review which will provide a more robust record of document management.

5.	GQ2(a)	Quarterly audits are carried out to cover documentation updates, premises, facilities and equipment and staff training. Specimen audits are referenced within the audit SOP but are not covered in the audit schedule. The DI is advised to include audits of specimens held under the licence which will allow the establishment to assure itself that specimens and records are fully traceable. Auditing procedures are documented within an SOP (SOP-09) which contains an audit template covering areas to audit, previous actions and an action plan. To support traceability assurance, the DI is advised to include a template which covers specimen ID, storage location and associated records.
6.	PFE2(d)	All material held under the licence is stored at room temperature. Details for how to move specimens within the Medical School are covered within an SOP (SOP-07) but the document does not detail specifically the location of the contingency storage room. The DI is advised to include in this document the location of the general storeroom, which is the primary contingency storage facility.

Background

Brunel University London has been licensed by the HTA since December 2021. This was the first routine inspection of the establishment. Since the licence application assessment, there has been a change of the Corporate Licence Holder contact in August 2024.

Description of inspection activities undertaken

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

Standards assessed against during inspection

41 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).
Some standards relating to consent were not applicable as the establishment does not seek consent directly from donors (C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)).

Review of governance documentation

The Regulation Manager reviewed the establishment's self-assessment document provided by the DI and team. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures (SOPs), the quality manual, training documentation, the Code of Conduct, audits, incidents and risk assessments. During the site visit, the establishment's electronic sample traceability system was also assessed.

Visual inspection

The Regulation Manager undertook a site visit inspection of the premises which included the Anatomy Academic Laboratory and the specimen storage area.

Audit of records

The Regulation Manager undertook traceability audits for ten specimens stored within the Anatomy Academic Laboratory storeroom. This included seven plastinated specimens and one bone specimen. Traceability details were crosschecked between the two identification tags on the specimen and information on the electronic records. No discrepancies were identified.

Meetings with establishment staff

The Regulation Manager met (virtually and in person) with staff carrying out activities under the licence. This included the Head of Anatomy, the Technical Manager, the Laboratory Technician, a Senior Lecturer in Anatomy and the Director of Academic Affairs who is the establishment's DI.

Report sent to DI for factual accuracy: 7 April 2025

Report returned from DI: 10 April 2025

Final report issued: 16 April 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: 7 May 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.