Inspection report on compliance with HTA licensing standards
Inspection dates: **17 September 2024 (remote) and 2 October 2024 (site visit)**

Brighton and Sussex Medical School

HTA licensing number 12687

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Brighton and Sussex Medical School	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.

Brighton and Sussex Medical School ('the establishment') was found to have met all HTA standards.

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

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 practice:

Number	Standard	Advice
1.	C1 (c)	The establishment do not directly seek consent from donors, however the consent forms and written information is agreed between the establishment and a third party. The public display consent form is currently being reviewed and updated. The DI is advised to cross-reference the public display consent documentation within the anatomical examination consent documentation as often the consenting for these two activities take place together.
2.	GQ2(a)	To provide greater assurance on security, the DI is advised to expand the range of internal audits to include audits of security measures and facility access records at the site.

Background

Brighton and Sussex Medical School has been licensed by the HTA for public display since June 2019. This was the second public display assessment of the establishment; the most recent previous inspection was during the licence application in May 2019.

Since the previous inspection, there have been significant changes to the licence. These include changes to the Designated Individual in November 2022, May 2023 and October 2023.

Description of inspection activities undertaken

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

Standards assessed against during inspection
32 out of 36 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(a), C1(b), C2(a), and C2(b)).

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures (SOPs), policies, the anatomy suite Code of Conduct, quality manual, training requirements and risk assessments. During the site visit, the establishment's electronic sample traceability system and database were also assessed.

Visual inspection
The inspection team undertook a site visit inspection of the premises which included the facility entrance, the preparation room, storage areas, office area and dissection rooms where public display takes place.

Audit of records
The inspection team undertook traceability audits for cadavers and specimens in the department. This included two skeletons, three potted specimens and consent for one full body donor. Traceability details were crosschecked between the identification tags and information on the electronic and paper records through to consent documentation (if applicable). No discrepancies were identified.

Meetings with establishment staff
Te inspection team met with staff carrying out activities under the licence. This included the Anatomy prosector, Anatomy lecturers, Head of Anatomy, Deputy Head of Anatomy, the Anatomy Administrator, the Dean of the Medical School, the Deputy Pro-vice Chancellor, and the Professor of Anatomy who is also the Designated Individual (DI).

Report sent to DI for factual accuracy: 14 October 2024

Report returned from DI: 16 October 2024

Final report issued: 17 October 2024

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.