

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 (BSMS)

HTA licensing number 12098

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
Brighton and Sussex Medical School (BSMS)	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.

Brighton and Sussex Medical School (BSMS) ('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 practices:

Number	Standard	Advice
1.	GQ1(a)	The standard operating procedure (SOP) for the 'Maintenance of Cadavers' details that condition checks take place every six weeks; however, this is routinely every four weeks. The DI is advised to resolve this at the next document revision.
2.	GQ2(a)	To provide greater assurances 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.
3.	GQ6(a)	The establishment has a robust suite of risk assessments covering licensed activities, with mitigating actions included. To strengthen linkages between risks and mitigations, the DI is advised to consider including references to staff training and the pertinent SOPs.

Background

Brighton and Sussex Medical School has been licensed by the HTA since July 2007. This was the third inspection of the establishment;

the most recent previous inspection took place in October 2021.

Since the previous inspection, there have been 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 inspection team 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 inspection team reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. These 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, dissection rooms, the preparation room and the office area.

Audit of records

The inspection team undertook traceability audits for cadavers and specimens in the department. These included one dissected body stored for a training course, one whole cadaver stored for anatomical examination, three prosections, two skeletons and four potted specimens. 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

The 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 and the Deputy Pro-Vice Chancellor who is also a Professor of Anatomy and the Designated Individual (DI).

Report sent to DI for factual accuracy: 10 October 2024

Report returned from DI: 16 October 2024

Final report issued: 16 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.