Inspection report on compliance with HTA licensing standards
Inspection date: **30 April 2025**

Birmingham Dental Hospital and School of Dentistry

HTA licensing number 12313

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	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
Birmingham Dental Hospital and School of Dentistry	Licensed	Not 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 Birmingham Dental Hospital ('the establishment') was found to have met the majority of HTA standards, four minor shortfalls were identified against Consent and Governance and quality system standards. These were in relation to consent procedures, standard operating procedures (SOPs), document control and audits.

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 shortfall identified during the inspection.

Compliance with HTA standards

Minor shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	The establishment collects and stores teeth following dental extractions. Patients are asked for their spoken consent to store and use their teeth for research and training purposes prior to tooth extraction, with evidence of their consent documented in the patient notes. There is a procedure which describes the process for documenting consent; however, it was found that consent-seekers did not consistently record evidence of consent.	**Minor**

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	The establishment collects teeth and other relevant material from patients following different clinical pathways. The processes for seeking consent, collection and storage of the teeth and other relevant material are different for each pathway but they were not described clearly in the documented procedures.	**Minor**

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	During the inspection, it was noted that there were two versions of DRTB-LAB SOP-004 (Tooth Collection); both copies shared the same version number and a different review cycle.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	Although the establishment had carried out annual audits of number of ‘waste’ teeth stored and distributed, there were no audits focussing on compliance with HTA standards or establishment processes.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment has introduced electronically-recorded consent, which involves the consent form being completed using an electronic device. Once the consent form is submitted, the patient is unable to make any amendments to their consent unless new consent is sought. The documented procedure on consent does not include steps to be followed if new consent is to be sought. The DI should consider reflecting this in the documented procedure, DRTB-DEN-SOP-001.
2.	C1(a)	The human tissue section (section 7.13) of the Birmingham Community Healthcare Consent Policy (BCHC Consent-Policy-V5.1) references body donor consent forms and contains non-functional hyperlinks. The DI is advised to review the policy and ensure necessary amendments are made.
3.	GQ3(a)	Although all staff are trained prior to working with human tissue, the DI is advised to ensure that competency assessments for staff working in the biobank are documented to provide evidenced assurance.

Background

The establishment is a dental hospital that treats over 120,000 patients each year. With consent, the establishment collects extracted teeth and other relevant material and stores them in an ethically-approved research tissue bank. Teeth are distributed for research use. The establishment also purchases material from outside of the UK, under an agreement.

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, 46 were assessed (standards published 3 April 2017). PFE2(b) was not applicable as the establishment does not stored material from deceased donors.

Review of governance documentation

A number of documents were reviewed during the inspection roundtable meetings 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, incidents and agreements.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members. During the meeting, the DI delivered a slide presentation, which served to facilitate a structured discussion on the PFE standards. The presentation and discussion covered key areas including security protocols, storage conditions, equipment maintenance, contingency planning, and procedures for cleaning and decontamination.

Meetings with establishment staff

Roundtable discussions were carried out with the DI and members of staff involved in licensable activities.

Report sent to DI for factual accuracy: 27 May 2025

Report returned from DI: 6 June 2025 (with comments)

Final report issued: 11 June 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.