

Licence application assessment report on compliance with HTA licensing standards

Assessment date: **16 December 2021**



**Brunel University London**  
Proposed HTA licensing number 12726

Application for a licence under the Human Tissue Act 2004

**Activities applied to be licensed**

<b>Area</b>	<b>Carrying out of an anatomical examination</b>	<b>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</b>	<b>Storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose</b>	<b>Storage of an anatomical specimen</b>
<b>Hub site Brunel University London</b>	Applied to be licensed	Not applied to be licensed	Applied to be licensed	Applied to be licensed

**Summary of visit findings**

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

Brunel University London ('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 proposed DI to consider the following to further improve practices:

<b>Number</b>	<b>Standard</b>	<b>Advice</b>
1.	GQ3 (b)	The establishment currently provides training on 'Working with Human Tissue', using a presentation developed to support training for staff working under the HTA research sector licence. To more suitably tailor the training, the proposed DI is advised to supplement it to include specific considerations for staff working under an anatomy sector licence; for example, as outlined in other establishment documentation and the HTA's Code of Practice C: Anatomical Examination.

### **Background**

The establishment has opened a custom-built anatomy suite, housed within the newly-established Brunel Medical School, a facility that will provide the teaching of human anatomy to undergraduate and postgraduate students. The new anatomy suite comprises a teaching laboratory and an anatomy store.

The collection of specimens to be held at the new facility includes plastinated specimens, skeletal material, and histological slides (formalin-fixed paraffin-embedded). All material will be stored at ambient temperature.

## **Description of activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk-based assessment:

### *Standards assessed against during visit*

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

### *Review of governance documentation*

Policies and procedural documents relating to all licensed activities, including standard operating procedures, risk assessments and traceability systems were assessed. Documents detailing the plans for staff training, adverse events, incidents, governance meetings and audits were also reviewed.

### *Visual inspection*

There was no site visit inspection associated with the licence application; however, photographs and site plans of the facility were provided.

### *Meetings with establishment staff*

The assessment also included meetings with the proposed Designated Individual (DI), the proposed Licence Holder contact (LHc), the proposed Persons Designated (PD), the Head of Anatomy, and a Clinical Anatomist who will be working under the licence.

**Report sent to proposed DI for factual accuracy: 20 December 2021**

**Report returned from proposed DI: 21 December 2021**

**Final report issued: 21 December 2021**

## **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.