Inspection report on compliance with HTA licensing standards
Assessment dates: **25 April (remote) and 26 April (site visit) 2022**

Royal College of Surgeons of England

HTA licensing number 12423

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
Hub site **Royal College of Surgeons of England**	Licensed	Licensed	Licensed	Licensed

Satellite site **Natural History Museum**	Not licensed	Not licensed	Not 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 the Royal College of Surgeons (the ‘establishment’) had met the majority of the HTA’s standards, one minor shortfall was found against a standard relating to Governance and Quality systems (risk assessments).

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 assessment.

Compliance with HTA standards

Minor Shortfall

Standard	Inspection findings	Level of shortfall
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 all applicable risks relating to licensable activities including: • Loss of or damage to specimens • Loss of traceability • Storage of anatomical specimens and contingency arrangements • Transport of specimens to and from the establishment • Security arrangements	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The DI is advised to consider including procedural audits into the schedule. This would widen the scope of audits and may help to provide stronger assurance that practices are aligned with expectations.

Background

Although the establishment is licensed for the full suite of anatomy sector activities at the hub site, and storage only at the satellite site, the only activity taking place at both sites is storage of anatomical specimens for training and education purposes. Access to relevant material, by students and groups for education and training, must be pre-approved. Policies and procedures are in place to ensure that the premises are secure and that confidentiality is maintained. The establishment has been licensed by the HTA since February 2007. This was the second inspection of the establishment; the last one took place in January 2009.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in April 2019 and a new Person Designated (PD) has been added to the licence. In addition, the hub site was closed for five years while it underwent major refurbishment. Although the hub site has reopened, a training room that was added during the refurbishment is in the final stages of completion and will be open to trainees who will have access to relevant material for the purposes of education and training.

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 assessment:

Standards assessed against during the inspection

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

The following documents were reviewed: policies and procedural documents relating to licensed activities, audits, risk assessments for health and safety, adverse incidents, staff training records, visitor management policies and visitor codes of conduct.

Audits were also reviewed. Advice is provided about the scope of the audit schedule (see *Advice*, item 1).

Visual inspection

A visual inspection was conducted at the hub and satellite sites. This included storage locations and training rooms.

Audit of records

Forward and reverse audits were conducted at the hub and satellite sites for relevant material (records to location and location to records). This included five forward and one reverse at the hub site and three forward and one reverse at the satellite site. No discrepancies were found.

Meetings with establishment staff

The inspection included discussions with the staff carrying out processes under the licence. This included the DI, a PD, the Director of Museum and Archives and a Conservator.

Report sent to DI for factual accuracy: 16 May 2022

Report returned from DI: 27 May 2022

Final report issued: 30 May 2022

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: 3 October 2022

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions

- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.