Inspection report on compliance with HTA licensing standards
Inspection date: **12 February (remote) and 14 February (site visit) 2024**

AECC University College
HTA licensing number 12070

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
AECC University College	Licensed	Not 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.

Although the HTA found that AECC University College ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems. The shortfalls related to standard operating procedures (SOPs) and 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 shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified 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.	There was no specified review period for SOPs and several SOPs did not reflect current processes or include sufficient detail to enable staff to follow the procedure from beginning to end and ensure uniformity between staff. For example, the SOP related to: • the prosection suite and security stated that relevant material is stored in another location outside of the prosection suite - this was not correct. • Monitoring temperatures stated that the fridge temperature should be recorded weekly but did not describe how this should be recorded, or what to do if the temperature is outside of the permitted range when the fridge has not been accessed. • Disposal of human tissue did not reference a current HTA Code of Practice. • Risk assessments focused on health and safety issues and did not include an assessment of other risks associated with licensable activities.	**Minor**

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 were primarily focused on health and safety issues and did not consider the risks associated with the licensed activities.	**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 establishment has an agreement with another HTA-licensed establishment for their staff to undertake an annual audit of the prosections held on site. In 2020 and 2021, due to COVID restrictions, this audit was undertaken by AECC University College staff, and there was no audit undertaken in 2023. For clarity and consistency, the DI is advised to seek an assurance that future audits will be conducted as specified in the agreement, or to develop a process for AECC University College staff to undertake the annual audit.

2.	GQ2(a)	The DI is advised to increase the scope of internal audits to include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect current practices and to identify areas for improvement. In addition, to provide greater assurances on security, the DI is advised to include audits of security measures and where possible, facility access records.
3.	N/A	The DI has been assured that all skeletal material at the establishment is more than 100 years old and does not need to be held under the licence. The DI is advised to formally document this assurance.

Background

AECC University College provides specialist teaching of chiropractic and diagnostic ultrasound to undergraduate and postgraduate students. The establishment receives specimens which are loaned under an agreement from another HTA-licensed establishment that takes responsibility for ensuring appropriate consent is in place and undertakes annual audits of the loaned specimens. In addition to embalmed specimens, the establishment has a collection of potted specimens and a collection of histology slides that were previously used for teaching purposes. While the establishment has a collection of skeletal material, these are all more than 100 years old and are not currently held under the licence.

AECC University College has been licensed by the HTA since 2007. This was the second inspection of the establishment; the most recent previous inspection took place in August 2013.

Since the previous inspection, the establishment has appointed a new Corporate Licence Holder contact, and a new DI on two occasions.

Description of inspection activities undertaken

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

Standards assessed against during inspection

38 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)), standards relating to consent training (C2(a), C2(b) and C2(c)), and standards related to disposal (T2(a) and T2(b)) were not applicable as the establishment does not directly seek consent from donors or dispose of material.

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures, equipment maintenance and monitoring, and traceability systems were assessed. Documents detailing staff training, adverse events, incidents, governance meetings, and the agreement with the establishment providing loaned specimens and undertaking the annual internal audit, were also reviewed.

Visual inspection

The site visit included a visual inspection of the prosection laboratory, including the areas where anatomical specimens and relevant material are stored and used for training.

Audit of records

An audit was undertaken of records and labelling for three prosections, three potted specimens, and one histology slide. There was full traceability for all material.

Meetings with establishment staff

The inspection included discussions with the DI, the Corporate Licence Holder contact, and other staff working under the licence including a PD working in the prosection laboratory, establishment staff responsible for granting access to the areas where licensable activities occur, and the Health and Safety Officer.

Report sent to DI for factual accuracy: 26 February 2024

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 21 March 2024

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: 8 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.