Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **11 January 2023**

College of Medicine and Dentistry

Proposed HTA licensing number

12746

Application for a licence under the Human Tissue Act 2004

Activities applied to be licenced

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
College of Medicine and Dentistry	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.

Although the HTA found that the College of Medicine and Dentistry (the establishment) had met the majority of the HTA's standards, xx minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

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 site visit.

Compliance with HTA standards

Minor Shortfalls

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.	Procedural documents did not contain enough information to enable a member of staff to follow a process from beginning to end. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
b) There are documented induction training programmes for new staff.	There was no documented induction training for new starters who will be carrying out licensable activities in the surgical skills laboratory.	**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.	The establishment has not carried out any risk assessments for the practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	There was no system in place for assigning a unique code to receipted material. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner.		
b) The date, reason for disposal and the method used are documented.	The system for managing receipt-to-disposal traceability did not include the documentation of date, reason and method for disposal. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The proposed DI should keep all procedural documents under review after licensed activities commence to ensure that they reflect practices, giving enhanced consideration to the following: i) Management of material that may not meet documented acceptance criteria; ii) Thawing of specimens in preparation for use.
2.	GQ1(d)	The proposed DI plans to hold regular meetings, which will focus on operational issues, including adverse events, changes to procedures and facilities issues. The proposed DI may also wish to consider adding audits and risk assessments as standing agenda items to ensure these can also be brought to the meetings.
3.	GQ2(b)	The proposed DI has put in place an SOP which describes the process of conducting audits. The audits will take place twice each year, with a focus on traceability. To support a consistent and comprehensive approach

		to auditing, the proposed DI should consider implementing standardised auditing documents and also consider including process audits to ensure that staff are undertaking activities in line with documented procedures.
4.	GQ4(a)	The establishment will work under the University's Records Management Policy. The proposed DI should review this policy to clarify retention periods for records relating to the surgical skills activity, as this is a new activity for the College.
5.	GQ5(a)	The establishment has an SOP for the management of adverse events. To strengthen staff awareness of the types of adverse events that may be relevant to HTA-licensed activites, the proposed DI should consider adding the following examples: - specimen loss - missing or incorrect documentation - security breach - abnormalities in storage temperature readings - inappropriate disposal
6.	PFE2(b)	Human material will be stored for the duration of the course and thereafter in a -40 degrees Celsius freezer, which contains several draws. The proposed DI should consider numbering each draw to assist traceability of specimens in storage.

Background

The establishment is a post-graduate dental teaching facility. The establishment will import cadaveric material for storage and use for surgical skills training. They plan to run courses lasting up to three days, every week each term. Following use, material will either be returned to the supplier or managed by the establishment in line with the wishes of the donor and/or their family.

The establishment also plans to store other tissue for research.

Description of activities undertaken

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

Standards assessed against during visit

Of the 47 standards, 45 standards were assessed. Standards T1(f) and (g) were not applicable as transportation will be managed by the supplier and there are no plans for send material to others.

Review of governance documentation

Key policies and procedural documents relating to licensed activities were reviewed. These included SOPs relating to receipt, storage, use and disposal of cadaveric material, agreement with the supplier and traceability system.

Visual inspection

A visual inspection of the surgical skills facility was undertaken. The facility has privacy glass, meaning that it is not possible for anyone to see into the laboratory. The laboratory remains locked and accommodates the -40 degrees Celsius freezer. The freezer was under warranty as it had been purchased in December 2022 and is attached to a back-up power device in case of failure.

Meetings with establishment staff

A meeting was held with the proposed DI to review the application and supporting documents.

Report sent to proposed DI for factual accuracy: 6 February 2023

Report returned from proposed DI: 23 February 2023

Final report issued: 27 February 2023

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: 21 June 2023

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, or;
   - 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, or;
- 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.