Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **16 July 2026 (site visit)**

University of Hertfordshire

Proposed HTA licensing number 12827

Application to be licensed under the Human Tissue Act 2004

Activities

Premises/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
University of Hertfordshire	Application made	Application not made	Application made	Application not made

Summary of 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.

University of Hertfordshire (‘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:

Number	Standard	Advice
1.	GQ2(a)	The Head of Technical Services will carry out annual audits against the HTA standards. The proposed DI and PD will be responsible for undertaking regular spot-checks of the plastinated specimens, throughout the academic year, to ensure that labels are attached appropriately and to ensure that the condition of the specimens is monitored. The proposed DI is advised to document findings to ensure there is an audit trail.
2.	GQ5(a)	The standard operating procedure (SOP) “AN-HTA-006 procedure”, describes how incidents and near-misses are managed and includes the requirement to report HTA Reportable Incidents (HTARIs) to the HTA within five working days. To strengthen the procedure, the proposed DI should ensure that the reporting to the HTA also includes incidents that may fall under the definition of a near-miss, as this is not clear in the current version. This will ensure that staff are aware that both HTARIs and near-misses require reporting to the HTA.
3.	PFE2(d)	The plastinated specimens will be stored in a dedicated room within the Anatomy facility the plastinated specimens would be relocated to another secure and monitored storage area in a different building on the same campus. The alternative storage location is in close proximity to the premises where licensable activity will take place, ensuring that transfer can be undertaken safely and efficiently. This will also help to ensure there is

		appropriate security and oversight of the specimens. The proposed DI is advised to review contingency SOP "HTA-AN-010" to ensure staff understand that specimens would not be used if stored in the contingency area

Background

The establishment is a university that will run a medical degree course from October 2026. The establishment will be storing over 100 plastinated teaching specimens that have been imported from outside of the UK. The plastinated specimens will be stored in a secure, access-controlled and temperature-monitored room, in a purpose-built facility. Teaching using the specimens will take place on a weekly basis, initially, and students will not directly handle the specimens. The establishment has appropriate on-site contingency arrangements for the specimens to be stored in an emergency. The establishment has no plans for students to undertake dissection work and plan to obtain more plastinated specimens in the future.

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 and site visit:

Standards assessed

Of the 47 HTA standards, 39 were assessed (standards published 3 April 2017). Standards C1(a),(b),(d),(e) and (f) and C2(a),(b) and (c) were not applicable as the establishment will not be seeking consent.

Review of governance documentation

A document review was undertaken and included: standard operating procedures relating to licensed activities, including; cleaning and decontamination, audits plans, risk assessments, incident management, contingency, transport, temperature monitoring and training and competency procedures.

Visual inspection

The visual inspection focused on access control to areas where material would be stored and the teaching area where plastinated specimens would be placed for teaching. In addition other areas were also visited, which included an interactive room and a clinical skills facility students containing hospital beds.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI, Person Designated and the Head of Technical Services.

Report sent to proposed DI for factual accuracy: 10 August 2026

Report returned from proposed DI: 10 August 2026 (with comments)

Final report issued: 11 August 2026

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, and;
- 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 inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- 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.