

Licence application assessment report on compliance with HTA licensing standards  
Assessment dates: **12 February (remote) & 27 February (site visit) 2026**



**Ellison Institute of Technology Oxford**  
Proposed HTA licensing number 12821

Application to be licensed under the Human Tissue Act 2004

**Activities**

<b>Premises/area</b>	<b>Storage of relevant material which has come from a human body for use for a scheduled purpose</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>Winchester House</b> <b>Ellison Insitute of Technology (EIT) Oxford</b>	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.

Although the HTA found that Ellison Institute of Technology ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and quality systems.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

## Compliance with HTA standards

### Minor Shortfalls

Standard	Assessment findings	Level of shortfall
<b>GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process</b>		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	There was no procedural document for transportation of HTA relevant material to external recipients.  <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i>	<b>Minor</b>

### Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment had a robust consent policy in place and a process to acknowledge, cascade, and document when a donor withdraws consent, and also includes disposal of the corresponding material. This process was not referenced in the relevant procedural document. The proposed DI is advised to ensure the consent policy encompasses all relevant consent procedures and practices, including the processes involved in handling consent withdrawals.
2.	GQ2(a)	There was a comprehensive audit schedule, structured around HTA standards. However, the plan alluded to standards that did not reflect the current HTA licensing standards for the research sector. The proposed DI is

		advised to amend the audit plan to ensure that the correct and up-to-date standards are being reviewed and evaluated.
3.	T1(b)	The establishment's register of materials is maintained in the Laboratory Information Management System (LIMS). Information entered on this database is manually transcribed by staff and hence subject to transcription errors. At present, the proposed DI performs a Quality Check (QC) of the entries to gain assurance of its accuracy and completeness but such checks were not routinely recorded. The proposed DI is advised to document the QC activity being undertaken to ensure records are verified thereby maintaining robust sample traceability.

### **Background**

Ellison Institute of Technology (EIT) is an Oxford-based company currently developing analytical assays, with a future focus on rapid diagnostic assays using molecular approaches for infectious disease diagnosis. The programme requires human material to be analysed and stored. Samples will be sourced from commercial suppliers as well as academic and healthcare partners.

### **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 licensing standards that were covered during the assessment (standards published 3 April 2017), 39 were assessed. C1(a), (b), (e) and (f) and C2(a), (b), and (c) were not applicable as the establishment is not involved in seeking consent for research within the scope of the Human Tissue Act 2004. PFE2(b) is not applicable as the establishment will not be storing material from the deceased.

#### *Review of governance documentation*

Local policies and procedural documents relating to licensed activities, template transfer agreements, equipment service records, audit plans, risk assessments, meeting minutes, temperature monitoring for the storage units, and staff training records were reviewed.

*Visual inspection*

The visual inspection comprised of reviewing the premises, 'goods in' area, laboratory, and sample storage facilities. A discussion took place on the sample journey and the responsibilities of staff receiving samples.

*Meetings with establishment staff*

A roundtable meetings were held with the proposed DI, proposed PDs, Quality, Legal, and Facilities teams supporting the application process.

**Report sent to proposed DI for factual accuracy: 19 March 2026**

**Report returned from proposed DI: 30 March 2026**

**Final report issued: 01 April 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.