Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **25 August (remote) and 28 August 2026 (site visit)**

Cyclana Bio Ltd

Proposed HTA licensing number 12837

Application to be licensed under the Human Tissue Act 2004

Activities

Premises/area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Cyclana Bio Ltd	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 Cyclana Bio Ltd ('the establishment') had met the majority of the HTA's standards, six minor shortfalls were found against standards for Consent, Governance and quality systems, 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 assessment.

Compliance with HTA standards

Minor Shortfalls

Standard	Assessment findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	The Informed Consent Form (ICF) for one of the research studies included a clause for seeking consent for storage of genetic material, but did not have any reference to storage of HTA relevant material. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
b) There is a document control system.	The majority of the procedural documents had no review dates, pagination, or author and reviewer names. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ2 There is a documented system of audit		

Standard	Assessment findings	Level of shortfall
a) There is a documented schedule of audits covering licensable activities.	The audit plan did not include review of consent forms or consent assurances in place for storage of human material. In addition, although the audit schedule included review of operational procedures, it did not describe how the audit will be carried out to accurately assess actual practices and identify areas for improvement. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	The establishment conducts weekly traceability audits, one of which identified a missing sample from one of the current studies. This incident was not reported internally within 24 hours of discovery, as required by the establishment's Adverse Event Standard Operating Procedure (SOP), and therefore did not allow for a timely investigation. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		

Standard	Assessment findings	Level of shortfall
c) Storage conditions are monitored, recorded and acted on when required.	There was no approved lone working policy in place at the time of inspection, to ensure staff safety when working within the liquid nitrogen storage area. Although a buddy system had been implemented in practice, the lone working policy remained in draft form awaiting formal review and ratification. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
d) There are documented contingency plans in place in case of failure in storage area.	The contingency plan did not define the stepwise process of transferring samples to contingency storage equipment or the threshold at which the contracted external storage facility should be utilised. *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.	C2(c)	A competency assessment process was in place for consent-seekers and successful completion was evidenced by an authorisation granted by the proposed DI, permitting personnel to obtain consent for specific studies.

		However, the framework did not define the competencies required for sign-off or specify the aspects of the consent-seeking procedure that were evaluated. The proposed DI is advised to establish the assessment criteria that define the knowledge, skills, and competencies that must be demonstrated by staff undertaking consent activities. The proposed DI is further advised to identify the assessment methods by which consent-seeking skills will be evaluated to ensure that only those who have demonstrated the required level of competence are authorised to seek consent.
2.	GQ1(c)	There were change control mechanisms in place for new operational procedures being implemented and these were documented on the Quality Management System (QMS) database. This system was designed to capture the different aspects of change control namely – the review of risks involved, validation procedures to be undertaken, identification of training required, and review of results or outcomes. However, review of outcomes was configured only as an optional step in the QMS. The proposed DI is advised to review the quality system and consider amending the review of results from an optional to a mandatory action, to facilitate confirmation that the intended objectives have been achieved, and that any unintended consequences have been identified and addressed.
3.	GQ2(a)	Regular traceability audits were being conducted by the Laboratory Manager on a weekly basis, but these were not referenced within the formal audit schedule. The proposed DI is advised to incorporate these activities in the audit plan to ensure that audit findings are consistently documented, reviewed, and, where necessary, investigated and escalated appropriately.
4.	GQ3(b)	There was a documented induction training programme in place for new staff but it did not include HTA training. However, in practice, relevant staff had completed HTA training and training records were available to demonstrate compliance. The proposed DI is advised to update the *New Personnel Induction Checklist* to include HTA-related training as a mandatory training requirement for all staff involved in licensable activities, ensuring that the documented induction programme accurately reflects current practices.
5.	GQ6(c)	Risk assessments were published electronically and were kept in an accessible location within the establishment's online document management system. However, there was no process in place to actively disseminate these risk

		assessments to staff to make them aware of the risks involved in carrying out licensable activities. The proposed DI is advised to implement a system whereby risk assessments are assigned as mandatory reading to raise staff awareness. This may help prevent risks from materialising and inform the development of procedures and relevant documentation.
6.	PFE1(c)	There were documented cleaning procedures in place. However, on review of records, gaps in the cleaning log for July 2026 were found and showed no evidence of routine cleaning being completed during this period. The proposed DI is advised to ensure regular review of such records to identify overdue activities and documentation gaps in a timely manner, enabling prompt investigation and implementation of corrective and preventative actions.
7.	PFE2(c)	There was a robust temperature monitoring and alarm system in place. However, there was no routine temperature trend review being conducted. The proposed DI is advised to implement a system allowing periodic review of temperature trends to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. In addition, manual challenge of temperature alarms was planned to be performed on an annual basis only. The proposed DI is advised to consider more frequent alarm challenge tests to ensure the system continues to operate effectively throughout the year. This could cover different seasonal conditions, when environmental temperatures may fluctuate over a wider range.
8.	PFE3(c)	Some equipment servicing activities and temperature probe calibration were performed internally and were documented on the establishment's QMS database. However, the database did not require calibration measurements to be entered into the system, and no predefined parameters had been established to determine whether a piece of equipment had passed or failed. The proposed DI is advised to define the acceptance criteria and measurement results for all internally-performed calibration activities to ensure their accuracy in assessing suitability of storage equipment.

Background

Cyclana Bio Ltd is a Cambridge-based company focused on advancing the understanding of endometriosis and developing novel treatments. This will be achieved through research into menstrual blood and other human materials. As the research programme develops, the work will require human tissue to be stored within the premises for extended periods, including long-term storage where necessary. The establishment will be sourcing the relevant material from a range of academic, commercial, and clinical collaborators.

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), 46 were assessed. 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, audit reports, incident records, risk assessments, samples management system, equipment service and calibration records, cleaning schedules, 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 and storing samples.

Meetings with establishment staff

Roundtable meetings were held with the proposed Corporate Licence Holder contact (CLHc), the proposed DI, proposed Person Designated (PD), and the wider scientific and technical team.

Report sent to proposed DI for factual accuracy: 24 September 2026

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

Final report issued: 24 September 2026

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: 24 September 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.