Licence application assessment report on compliance with HTA licensing standards
Assessment date: **22 July 2025 (remote) and 01 August 2025 (site visit)**

Kinomica Ltd

Proposed HTA licensing number 12808

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
Kinomica Ltd, Biohub, Alderley Park, SK10 4TG	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.

Kinomica Ltd ('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.	C1(c)	The establishment plans to purchase relevant human material from third-party suppliers. To ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice, the proposed DI is advised to strengthen consent-related assurances within agreements with these suppliers.
2.	PFE1(b)	Storage units designated for relevant human material were not equipped with locks. Although located within access-controlled areas, the proposed DI is advised to consider whether additional measures would enhance existing security arrangements.

Background
Kinomica limited is a precision medicine company focused on developing diagnostic tools for oncology. Its research involves the use of human material, including formalin-fixed paraffin-embedded tissue, blood samples, peripheral blood mononuclear cells, and bone marrow aspirates. At the time of the assessment, the establishment had sponsored projects with Health Research Authority Research Ethics Committee approval and had stored samples with a HTA-licensed third-party. The establishment has applied for a HTA licence for the storage of relevant material, which has come from a human body, for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.

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 (published 3 April 2017), 38 were covered during the assessment. Several standards relating to consent were deemed not applicable because the establishment had stated it will not obtain consent directly from donors. These include standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), and C2(c). Additionally, standard PFE2(b) was deemed not applicable, as the establishment had stated it will not store relevant material from deceased donors.

Review of governance documentation

Policies and procedures covering all licensable activities were assessed, including an overarching HTA compliance policy, standard operating procedures, third-party agreements, and risk assessments. Documentation relating to staff training, induction, incident and complaints management, governance meetings, and audits was also reviewed. In addition, the establishment's compliance management system was demonstrated and its plans for sample management as well as maintaining material traceability were evaluated.

Visual inspection

The Regulation Manager conducted a visual inspection of the premises, which included the reception area, laboratory spaces, storage facilities, and the goods-in mailroom. The inspection evaluated the adequacy of security measures, traceability practices, and the suitability of storage units, including contingency storage and temperature monitoring. Cleanliness and the availability of personal protective equipment were also assessed, and cleaning records were reviewed.

Meetings with establishment staff

The inspection included discussions with the proposed DI, quality assurance manager, procurement manager, proposed Corporate Licence Holder contact, proposed Persons Designated, mailroom staff, and researchers.

Report sent to proposed DI for factual accuracy: 19 August 2025

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

Final report issued: 22 August 2025

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.