Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **25 July (remote) and 29 July (site visit) 2025**

Caeruleus Genomics Ltd

Proposed HTA licensing number 12807

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
Caeruleus Genomics 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 Caeruleus Genomics Ltd ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and quality systems and Traceability.

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
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.	A comprehensive risk assessment was in place but did not include all risks to HTA relevant material associated with licensable activities. There was no documented risk assessment for potential loss of human tissue and for potential incorrect disposal of HTA relevant material. *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		
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	The establishment's audit trail of samples is maintained on an digital database. However, the information recorded in this system was incomplete. The database did not have a mandatory field to document the use to which the HTA relevant material was put. Additionally, there was no mechanism in place to capture details of transfer of samples from the establishment to external recipients. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

Standard	Assessment findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
d) A system is in place to ensure that traceability of relevant material is maintained during transport.	A Standard Operating Procedure (SOP) for transportation of HTA relevant material was in place but only referenced inbound sample shipments. There was no defined process in place to ensure sample traceability is maintained during onward transfer of human tissue. *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.	C1(c)	An SOP was in place governing consent assurances from external providers. This document listed acceptable evidence of consent which included Research Ethics Committee (REC) approval and HTA documentation. The proposed DI is advised to consider amending the SOP to update this list as the presence of these documents alone do not demonstrate that a valid informed consent was obtained in accordance with the requirements of the Human Tissue Act 2004 and the HTA's Codes of Practice.
2.	GQ1(b)	A system of document control was in place wherein governance documents included revision history, 'effective from' date, next review date, pagination, and author and reviewer names. Revisions of SOPs would be recorded in

		a cloud-based drive. However, this was not embedded in the live versions of the documents. The proposed DI is advised to incorporate a section for revision history on the SOP template indicating details of the amendments that have taken place to enable readers to keep track of the changes to processes and procedures.
3.	GQ2(a)	There was a robust system of audit in place. The establishment's Quality Manual mandated full vertical audit beginning from consent of the samples through to their disposal. In contrast, the audit SOP alluded to vertical audits being conducted from sample to storage location only and vice-versa. The proposed DI is advised to ensure consistency in the audit processes being implemented and that the documents governing these activities are clear and are aligned.
4.	GQ2(b)	The audit report template contained details of findings and follow-up actions allocated to staff. It also had references to corrective and preventative actions (CAPA) plans. However, the details of CAPA plan were captured in a separate incident log. The proposed DI is advised to consider linking the audit report template to the incident log where CAPA actions are clearly defined and documented.
5.	GQ3(a)	A training log was in place to keep records of staff attendance of training. This held core training records but did not include external training. The proposed DI is advised to keep complete records of training including attendance of professional meetings and external training events that enable staff to keep abreast of good practices in their areas of expertise.
6.	GQ3(b)	There was a documented induction training programme for new staff. However, this document was not controlled. The proposed DI is advised to include the induction checklist in their quality documents subject to version control, approval, and regular review.
7.	GQ3(d)	The establishment indicated plans to introduce an annual staff performance review. However, this was not in place at the time of the licence application assessment. The proposed DI is advised to ensure staff have training and development plans and that these are reviewed periodically.

8.	GQ5(b)	The establishment's adverse event and risk management SOP described incident management systems. It mandated the reporting of incidents using an adverse event form. However, this form was not a controlled document. The proposed DI is advised to include this in their quality documents subject to version control, approval, and regular review.
9.	PFE3(a)	The establishment recently procured equipment and were not yet under service contracts. Consequently, storage location of validation, calibration, maintenance, and monitoring records were not yet determined. The proposed DI is advised to ensure equipment is subject to recommended servicing and regular maintenance, and to ensure a central location is allocated where corresponding records will be kept.
10.	PFE3(b)	Staff would be made aware of how to report equipment problems through the induction programme. However, the staff induction checklist had no references to equipment management. The proposed DI is advised to update the induction checklist to include equipment failure reporting procedures to facilitate timely renewal of unsuitable items.

Background

Caeruleus Genomics Ltd is an Oxford-based company specialising in advanced molecular characterisation of various types of human tissue, to generate a deeper understanding of human biology and inform future therapeutic research in chronic conditions. The establishment will be sourcing materials from NHS hospitals, academic collaborators, biobanks, and commercial providers from the UK and abroad. The company also has plans on establishing a research tissue bank 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 licensing standards that were covered during the assessment (standards published 3 April 2017), 38 were assessed. C1(a), (b), (e), (d) 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 material transfer agreements, audit plans, risk assessments, meeting agenda items, incident logs, and staff training records were reviewed.

Visual inspection

The visual inspection comprised of reviewing the laboratory premises, sample storage areas, ‘goods in’ area, and emergency storage area. A discussion took place on the sample journey, processes involved in receiving samples, temperature monitoring, and equipment maintenance.

Meetings with establishment staff

A roundtable meeting was held with the proposed Corporate Licence Holder contact (CLHc), the proposed DI, and the Founder Associate supporting the application process.

Report sent to proposed DI for factual accuracy: 12 August 2025

Report returned from proposed DI: 12 August 2025

Final report issued: 13 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.