Licence application assessment report on compliance with HTA licensing standards
Assessment date: **12 September 2025**

DNAe @ Scale Space

Proposed HTA licensing number 12810

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
DNAe @ Scale Space	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.

The HTA found that DNAe @ Scale Space ('the establishment') met almost all of the HTA's standards. One minor shortfall was identified against Governance and quality systems standards, due to the limited scope of risk assessments covering HTA licensable activities.

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 shortfall 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		
GQ6(a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice	The establishment had not documented risk assessments for all activities that will be carried out under the licence. *"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.	GQ1(a)	Human tissue that has been donated for research with consent will be imported from the USA and UK approved suppliers. The DI should consider documenting the agreed process that should be followed to remove samples from storage should a participant withdraw their consent. This will ensure that staff adhere to a consistent process.
2.	GQ3(b)	There is an induction process for staff involved in licensable activities. Staff are also expected to have read all procedures and HTA Codes of Practice. To strengthen the approach to training, the DI should consider making staff aware of wider learning that is publicly available.
3.	T2(b)	Blood samples will be lysed during use in research at the establishment and will be used-up during testing, meaning that there is no planned disposal of relevant material. The DI should consider adding a column to the sample inventory for the disposal reason to be documented if samples are disposed of for other reasons.

Background

The establishment is a private company that specialises in the development of new technologies to improve patient care. They plan to receive blood samples from the USA, which will be received and stored for research purposes with consent.

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, 39 were covered during the assessment (standards published 3 April 2017). Standards C1(a),(b),(d),(e) and (f) and C2(a),(b), (c) were not applicable as the establishment will not be involved in consent seeking. PFE2(b) is not applicable as the establishment does not intend to store tissue from deceased donors.

Review of governance documentation

Local policies and procedural documents relating to licensable activities, contracts for servicing of equipment and records of servicing, the audit schedule, health and safety risk assessments and plans for staff training were reviewed.

Visual inspection

The visual inspection included review of the storage areas where human tissue would be stored and security access to the building.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI and establishment staff supporting the application process.

Report sent to proposed DI for factual accuracy: 3 October 2025

Report returned from proposed DI: 9 October 2025 (with comments)

Final report issued: 13 October 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.