Inspection report on compliance with HTA licensing standards
Inspection date(s): **12 June 2025**

ProAxsis Ltd

HTA licensing number 12667

Licensed under the Human Tissue Act 2004

Licensed activities

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
ProAxsis Ltd	Licensed	Not licensed

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that ProAxsis Ltd ('the establishment') had met the majority of the HTA's standards, six minor shortfalls were found against Governance and quality systems, Traceability, and Premises, facilities and equipment standards. These related to standard operating procedures (SOPs), document review, governance meetings, auditing, traceability of samples and the establishment's storage contingency plan.

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 inspection.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	The establishment's SOPs relating to licensable activity did not reflect current practices, information being out-of-date – due to infrequent review - or incomplete. For example, although the establishment does not seek consent for donations directly, the procedure in place to detail how the establishment ensures consent has been obtained by third parties was not documented.	**Minor**
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	Meetings are not formalised and the establishment was unable to provide evidence of regular governance meetings where matters relating to HTA-licensed activities are discussed.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	The establishment have a newly developed audit schedule however was unable to provide evidence of any audits being carried out for material stored under the licence.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments are reviewed regularly	The establishment's risk assessment relating to licensable activity had not been reviewed since it was developed in 2017. As a result, some information contained within it was out-of-date and did not reflect current practices.	**Minor**
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		

b) A register of donated material, and the associated products where relevant, is maintained	The establishment's electronic register for samples in storage had not been maintained. In the absence of any evidence of internal audits, a traceability audit was requested. The audit identified that although original 'parent' samples were routinely recorded, some samples that had been processed and re-aliquoted were not recorded.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area	Although the documented contingency plan had never needed to be used, it was deemed unsuitable. Local arrangements included the transfer of samples to another freezer on the site; however, there is not sufficient capacity in any other freezer. There was also an agreement to transfer samples to a different premises that were not HTA-licensed. In the event of a storage equipment failure, there is a risk that samples would become harmed or unusable.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Documents, including SOPs, are only redistributed to staff if changes are made during the review process. The DI may wish to consider redistributing regardless of whether there have been changes made to ensure that staff are fully trained and up-to-date on policies and procedures relevant to their work.
2.	GQ3(d)	The establishment does not document staff appraisals and personal development plans. The DI is advised to formalise staff evaluation processes to provide a more structured platform for feedback, goal-setting and career development.

3.	T1(c)	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the DI is advised to consider improving signs on the freezers highlighting that human samples are contained within.

Background

ProAxsis Ltd has been licensed by the HTA since September 2017. This was the third inspection of the establishment; the most recent inspection was an Evaluated Self-Assessment (ESA) and took place in December 2024. Since the previous inspection, there have been some significant changes to the personnel named on the licence including the Corporate Licence Holder contact (CLHc) in March 2025 and April 2025.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

36 of 47 HTA licensing standards were covered during the licence assessment (standards published 3 April 2017).

- Some standards relating to consent were not applicable as the establishment does not seek consent directly from donors (C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)).
- Due to a lack of an audit schedule, GQ2(b) could not be assessed.
- GQ3(c) was not relevant as the establishment does not have visiting staff.
- PFE2(b) was not relevant as the establishment does not store the deceased.

Review of governance documentation

Policies and procedural documents relating to all licensed activities were reviewed. This included overarching SOPs, the employee's handbook, risk assessments, training records and cleaning schedules.

Visual inspection

There was no site visit inspection associated with the assessment; however, a virtual meeting took place to discuss compliance with the Premises, facilities and equipment (PFE) standards and photographs of the storage facilities were provided.

Audit of records
As there was no site visit inspection associated with the assessment and no internal audits available for review, the DI was asked to complete an audit for twenty, randomly-selected samples in storage. Discrepancies were identified for three samples whereby samples had been logged in the establishment's freezer map paper records but not on the electronic system (*see shortfall against Standard T1(b)).*

Meetings with establishment staff
The assessment included discussions with the Chief Operating Officer (COO) who holds the position of DI.

Report sent to DI for factual accuracy: 25 June 2025

Report returned from DI: 2 July 2025

Final report issued: 2 July 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
- 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
   - 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 inspection.

   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
- 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.