Inspection report on compliance with HTA licensing standards
Inspection date: **19 July 2022**

HistologiX Limited

HTA licensing number 12097

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
HistologiX Limited	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.

HistologiX ('the establishment') was found to have met most of the HTA's standards; however, two minor shortfalls were identified against standards for Governance and Quality Systems, with regards to, governance meetings and risk assessments.

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

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures as part of the overall governance process		
GQ1(d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	The establishment have not been holding governance meetings in respect of HTA-licensed activities. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

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 are in the process of validating a continuous temperature monitoring system for the freezers used to store human tissue, with the view to moving to an electronic system in due course. At present, no alarm testing of the freezers is carried out. However, in the event of a critical storage temperature failure, each freezer has a CO_2 back-up cylinder attached to it. There is no documented assessment of risk for storage failure or sample damage to determine whether existing and planned mitigations are adequate. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(d)	The establishment purchases tissue from two suppliers. There is an ethical statement in place confirming that the material from one of the suppliers is suitable to be used for research. There is no such statement in place for the other supplier, however, there is a statement on the quotation for human tissue samples that indicates that tissue has been collected in compliance with a number of regulations, including those under the remit of HTA and National Research Ethics Service. To ensure a consistent approach, the DI may wish to consider putting in place either a formal statement or agreement which helps to provide assurances around the material supplied.
2.	GQ1(a)	The DI is advised to review the standard operating procedure (SOP) which covers human tissue tracking to ensure it includes the transfer of tissue to Pathologists and how this is managed.
3.	GQ2(a)	The audit function is now managed in-house by a dedicated staff member. Audits have been carried out against a new audit schedule with a focus on process and premises. Historically the traceability audits have been carried out during the study audits, which moving forward will be carried out independently. To improve the approach to audits the DI may wish to include a thorough audit against HTA standards, which will enable staff to identify if current practices and processes continue to meet HTA standards.
4.	GQ6(a)	The DI may wish to consider reviewing the risk assessments of HTA-licensed activities to ensure that the control measures include evidence such as references to key policies and procedures which indicate a risk has been mitigated through these.

5.	PFE2(c)	Critical storage conditions and CO_2 levels for cylinders are monitored manually, however, the alarms are not tested at present. The DI is advised to include documented alarm testing to check that the audible alarm is working as expected.

Background

The establishment is an accredited laboratory with a particular focus on storing and using human tissue in drug discovery research. This was the third inspection of the establishment; the most recent previous inspection took place in 2017. The establishment had responsibility for hosting a Research Tissue Bank on behalf of a supplier. This activity has now ceased with most of the tissue being removed from the premises and managed at another HTA-licensed premises. Since the previous inspection, there have been no other significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

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

Standards assessed against during inspection

All 47 standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to, standard operating procedures for licensable activities, key policies, study audits including an audit against HTA standards, staff training records, records relating to traceability and incidents.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards.

Audit of records

No traceability audits were carried out; however, a review of the establishment's audits was undertaken as part of the assessment. The Regulation Manager had no concerns with the reports presented during the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff and included the CLHc and DI involved with licensed activities.

Report sent to DI for factual accuracy: 2 August 2022

Report returned from DI: 5 September 2022

Final report issued: 6 September 2022

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 Virtual Regulatory Assessment Report.

Date: 6 September 2022

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.