Inspection report on compliance with HTA licensing standards
Inspection date: **7 February 2023**

Autolus Limited

HTA licensing number 12642

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
Autolus 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.

Although Autolus Limited ('the establishment') was found to have the met most of the HTA's standards, three minor shortfalls were found against standards for Governance and quality and systems (standard operating procedures 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 shortfall identified during the assessment.

Compliance with HTA standards

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
GQ1(a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	There were no documents covering the practical elements of the establishment's traceability system and how it should be used. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	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	Risk assessments were not sufficiently detailed and did not include control measures, meaning it was hard to determine if risks were appropriately mitigated. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**
GQ6(b) Risk assessments are reviewed regularly	Risk assessments have not been subject to regular review.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment's consent form provides two options to the donor - one where consent is enduring and the other is time-limited. Although donors rarely provide time-limited consent, the consent procedure does not provide steps that should be taken by staff on handling material which has time-limited consent and the donor information sheet does not make these options clear. The DI is advised to consider how to make sure that required information is clearly described to both staff and donors.
2.	GQ2(a)	The establishment undertakes regular audits of traceability and has put in place an audit schedule for the year ahead. The DI is advised to consider the following to strengthen the scope of, and benefits from, auditing; i) each laboratory group to undertake traceability audits of their material; ii) observation audits of key processes; iii) audits focussing on compliance with HTA standards.
3.	T2(b)	The establishment has in place procedures that govern disposal of relevant material which require that reason, method and date of disposal must be recorded. The relevant material that the establishment stores is used up during the experiments and this is reflected in the traceability system. Although the establishment has not had to dispose of relevant material so far, the DI is advised to consider including other categories or options as reasons for disposal, such as participant withdrawal from research.

Background

The establishment is a private company that specialises in life sciences, with a particular focus on research into innovative therapies. The establishment stores blood samples and human peripheral blood leucopacks from other HTA-licensed establishments and suppliers. The healthy volunteer donors are staff that are managed on a donor registry, which is managed by the Designated Individual (DI).

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

Of the 47 HTA standards, 46 were assessed (standards published 3 April 2017). Standard PFE2(b) was not applicable as the establishment does not store tissue form the deceased.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff training competency records and records relating to traceability.

The establishment recently arranged an independent audit of their standards and, following this, put in place a number of corrective actions.

Visual inspection

A number of pre-recorded videos of HTA-licensed storage areas were shared during the assessment, which provided an overview of the security arrangements.

Audit of records

The establishment undertakes internal traceability audits, from record to storage and storage to record, on a regular basis

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI, PD and Facilities staff.

Report sent to DI for factual accuracy: 21 February 2023

Report returned from DI: 28 February 2023

Final report issued: 1 March 2023

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 Inspection Report.

Date: 17 April 2023

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.