Licence application assessment report on compliance with HTA licensing standards
Site visit date: **23 January 2024**

Logical Biological Ltd

Proposed HTA licensing number 12770

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

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
Logical Biological Ltd	Applied to be licensed	Not applied to be licensed

Summary of assessment 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 Logical Biological Ltd ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against one standard for Governance and quality systems, related to Standard Operating Procedures (SOPs).

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 visit.

Compliance with HTA standards

Minor Shortfalls

Standard	Assessment 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.	Several SOPs did not provide sufficient details to enable staff to follow the procedure from beginning to end, and ensure uniformity between staff undertaking the process. This included SOPs related to: • internal audits • creating and reviewing risk assessments • accessing contingency freezer units and transferring samples into the contingency freezers. In addition, while the establishment intends to source samples from external suppliers they may, on occasion, collect samples from donors. Although staff were appropriately trained, there was no SOP for obtaining consent. ***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.	T1(c)	After initial receipt checks, samples are placed onto a quarantine freezer shelf while paperwork is checked. Should any paperwork be missing, the samples will remain in the quarantine freezer while the issue is resolved. The proposed DI is advised to consider logging samples in quarantine into the establishment sample tracking database to ensure that there is an audit trail that records all sample storage locations.
2.	PFE2(c)	Considering the potential temperature variation within individual freezer units, the proposed DI is advised to review target storage temperature ranges, and the associated alarm thresholds, to provide an assurance that relevant material will be stored at appropriate temperatures.
3.	PFE2(c)	The proposed DI is advised to consider implementing a system where the temperature plots from the freezer monitoring system are regularly reviewed as this may identify any unexpected temperature trends, or indicate a potential failure of the units before it occurs.
4.	PFE2(c)	To support oversight of storage conditions, the proposed DI is advised to add the temperature alarm set points to signs on the -80°C freezers so that staff are visually reminded of minimum and maximum temperatures.
5.	PFE3(a)	While the ‘in use’ freezers are actively monitored, there is no monitoring of the back-up contingency freezers. The proposed DI is advised to monitor the temperature of the back-up freezers to provide an assurance they are working within required parameters should they be needed.

Background

Logical Biological Ltd has applied for an HTA licence to store relevant material which has come from a human body for use for scheduled purposes. The establishment intends to receive relevant material from suppliers who will take responsibility for seeking consent, but may also collect samples from donors in the future. Relevant material will be stored at ambient temperature or frozen at either -20°C or -80°C. In addition to a HTA licence, the establishment is accredited to ISO9001:2015.

Description of activities undertaken during the assessment

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

Standards assessed against during visit

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not intend to store the deceased (standards published 3 April 2017).

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, equipment records, risk assessments, arrangements for monitoring the storage units, a review of the proposed procedures for recording and tracking relevant material, a review of the sample tracking database, and staff training records.

Visual inspection

The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment and areas where samples will be stored.

Meetings with establishment staff

The assessment included meetings and discussions with the proposed Designated Individual (DI), the establishment Operations Manager, and other staff who will be working under the licence.

Report sent to proposed DI for factual accuracy: 7 February 2024

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 20 February 2024

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 site visit 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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.