Licence application assessment report on compliance with HTA licensing standards
Site visit date: **16 February 2023**

Flagship Labs 86 UK

Proposed HTA licensing number 12750

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
Flagship Labs 86 UK Suite 2, Newnham Building, Chesterford Research Park	Applied to be licensed	Not applied to be licensed

Summary of visit 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 Flagship Labs 86 UK (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems (documented policies and procedures), and Premises, facilities and equipment (temperature monitoring, premises security and contingency plans).

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 visit.

Compliance with HTA standards

Minor Shortfalls

Standard	**Visit 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 had no documented standard operating procedures (SOP) covering temperature monitoring, and specimen preparation/preservation. *The establishment submitted sufficient evidence to address the temperature monitoring SOP shortfall before the report was finalised.*	**Minor**

PFE1 The premises are secure and fit for purpose		
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.	The establishment did not have security in place to ensure fridges and freezers were secure from unauthorised access. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	The storage conditions for freezers and fridges were not monitored or recorded.	**Minor**
d) There are documented contingency plans in place in case of failure in storage area.	The establishment had identified the risks and mitigating factors associated with a failure in the storage area, but has not provided any documented contingency plans. *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)	The proposed DI is advised to include definitions of the disposal reasons within SOP_HTA-04 Disposal of Human Tissue to ensure staff have a consistent understanding of the disposal reasons and the reason for disposal is

		recorded correctly in all instances within the tissue tracking database. A disposal reason due to consent withdrawal should also be included.
2.	GQ1(a)	The proposed DI is advised to consider including a checklist template within SOP_HTA-03 Labelling, Recording and Tracking Human Tissue, detailing the checks to be carried out when receipting tissue at the establishment to ensure the same procedure is carried out by all staff.
3.	GQ1(a)	The proposed DI is advised to expand SOP_HTA-03 Labelling, Recording and Tracking Human Tissue to include the process steps of scanning and saving of consent documentation and relevant material delivery receipts to the tissue tracking database to ensure full audit traceability.
4.	GQ1(b)	The proposed DI is advised to include the name of the person who reviews SOPs on governance documents as confirmation the SOP reflects the process carried out.
5.	GQ1(d)	The proposed DI is advised to include a standing agenda item covering HTA licensable activities at quarterly Biological Safety Committee meetings to ensure activities involving relevant material are regularly reviewed.
6.	GQ2(b)	The proposed DI is advised to include timeframes for completing audit follow-up corrective and preventative actions within audit reports to ensure actions identified are resolved in a timely manner.
7.	GQ3(b)	The proposed DI is advised to expand the documented induction training programme for new staff to include a checklist identifying all training and induction requirements which is to be signed and dated by both the inductee and inductor to evidence completion and understanding of policies and procedures.
8.	GQ3(b)	The proposed DI is advised to include detailed training videos/notes on how to use the tissue tracking database as part of the induction training programme for new staff to ensure the database is used correctly consistently.
9.	T2(b)	The proposed DI is advised to create a drop down menu within the tissue tracking database to list the disposal methods for relevant material that align with options available within SOP_HTA-04 Disposal of Human Tissue to

		ensure only approved disposal methods are used.
10.	PFE2(c)	The proposed DI is advised to add signage to the freezers and fridges to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum temperatures. Signage should also include that the fridge/freezers are storing relevant material and details of the person to contact in case of equipment failure.

Background

Flagship Labs 86 UK (FL86) has applied for an HTA licence to store relevant material which has come from a human body for use for a scheduled purpose; namely, research in connection with disorders, or the functioning, of the human body. FL86 is a biotech company seeking to leverage advances in genetics to discover new therapeutic therapies for a wide range of human diseases.

Description of activities undertaken during visit

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

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 material from 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, risk assessments, adverse event reporting, training requirements, arrangements for temperature monitoring for the refrigerated units, and a review of the HTA tissue tracking database that will be used to record and track relevant material.

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 stored.

Meetings with establishment staff
The assessment included meetings and discussions with the proposed DI, the proposed Corporate Licence Holder contact, the Laboratory Operations Manager and the Data Infrastructure Manager.

Report sent to proposed DI for factual accuracy: 6 March 2023

Report returned from proposed DI: 7 March 2023

Final report issued: 11 April 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: 11 July 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 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.