Licence application assessment report on compliance with HTA licensing standards
Inspection date: **14 September 2022**

Foster + Freeman

Proposed HTA licensing number 12739

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
Foster + Freeman	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.

Foster + Freeman (the 'establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

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

Number	Standard	Advice
1.	C1(d)	The proposed DI is advised to consider adding contact details to donor consent forms to support the process for donors to withdraw their consent.
2.	PFE2(c)	The proposed DI is advised to add detail to the Standard Operating Procedure 'Monitoring & Testing of Storage Conditions' regarding the monitoring of the refrigerated storage temperatures using the ISO 17025 compliant thermometer probe, so that it reflects the process described during the assessment.
3.	PFE2(d)	There is an Uninterruptible Power Supply (UPS) available should there be an interruption to the power supply to the establishment. The proposed DI is advised to consider undertaking a risk assessment of the suitability of a single UPS for the two refrigerators located in different rooms and to consider documenting a process for consolidating all refrigerated relevant material into one refrigerator should it be necessary.

Background
Foster + Freeman is a forensic service provider that 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 undertake research and development using forensically relevant human blood and other biofluids. In addition to applying for an HTA licence the establishment is currently accredited to ISO 9001:2015 and ISO 14001:2015 standards.

Relevant material to be held under the licence will either be stored under refrigerated conditions or at ambient temperature.

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 assessment:

Standards assessed against during the assessment

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, arrangements for temperature monitoring for the refrigerated and ambient storage units, and a review of the HTA Sample Database that will be used to record and track relevant material.

Visual inspection

The assessment included a virtual review of the establishment facilities. This was undertaken through the use of a detailed floor plan that indicated all security and access points within the establishment. This was supplemented with photographs of the building, both internal areas where licensable activity will be undertaken, and external views of the building including the access points and fire exits. The floor plan detailed the establishment internal and external CCTV cameras, including their field of view in relation to the establishment, and was supplemented with photographs of the internal and external CCTV cameras, including photographs of the CCTV camera displays. The presentation also included photographs of the corridors leading to the storage areas, including the key fob access at all security doors that would be used to access the storage areas. Both areas proposed for storage of relevant material were photographed, clearly demonstrating the layout of the room and the units intended for refrigerated and ambient storage. This was supplemented with close up views of the refrigerators themselves, including the inbuilt temperature displays and additional monitoring system with visible temperature display. Photographs clearly indicated the location of appropriate signage, on the access doors to the room, and on the storage units themselves. Additional copies of the signage to be utilised were also provided for review.

Meetings with establishment staff
The assessment included meetings and discussions with the proposed DI, the proposed Corporate Licence Holder contact, a representative of the building facilities team, and a member of staff who will be working under the licence.

Report sent to proposed DI for factual accuracy: 10 October 2022

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

Final report issued: 25 October 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.