

Executive Licensing Panel - minutes

Centre 0011 (London Sperm Bank)

Variation of Licensed Premises

Wednesday, 7 October 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Helen Crutcher Laura Riley	Director of Finance and Resources Risk and Business Planning Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Matthew Mudford	Licensing Manager Scientific Policy Officer (Induction)

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

- 1.1.** The panel noted that the London Sperm Bank (LSB) has held a storage only licence with the HFEA since 2010, when they took over the former 'Louis Hughes' licensed centre. The centre is part of the London Women's Clinic (LWC) group, under the umbrella of JD Healthcare. The centre is now mainly a storage and distribution centre for donor sperm, providing sperm to clinics within the LWC group, other fertility clinics within the UK and internationally. The centre ceased actively recruiting donors in May 2017 and the donor recruitment for the LWC group moved to The Bridge Centre (centre 0070).
- 1.2.** The panel noted that, on 4 February 2020, a variation of licensed premises application was made by the Person Responsible (PR), to change its licensed premises and relocate to the basement floor of centre 0070. As part of this re-structuring, donor recruitment activities, which had been undertaken by centre 0070 since May 2017, were to revert to centre 0011; this application was approved by Executive Licensing Panel (ELP) on 16 June 2020. Special Directions were also issued, for a period of six months, to authorise gamete storage at the previous premises in Harley Street, so storage dewars could remain there until their relocation to the new premises at centre 0070, anticipating delays as a result of the Covid-19 pandemic.
- 1.3.** The panel noted that, following the lifting of Covid-19 restrictions, the centre experienced an unanticipated problem that thwarted their business operating model. Without warning, St Thomas Street, where the new centre premises are situated, was made a one-way system and a bicycle lane was introduced. This prevents the entry of larger vehicles onto St Thomas Street, including the larger nitrogen delivery vehicles, needed to deliver the quantity of nitrogen required to serve both centre 0070 and centre 0011 dewars. The PR has confirmed that delivery of smaller quantities of nitrogen required for dewars, held by centre 0070, remains uninterrupted due to distant parking and manual filling of transport dewars. The dewars belonging to centre 0011 had not been relocated to the St Thomas Street location and remain at the Harley Street premises.
- 1.4.** The panel noted that a decision has been made for centre 0011 to revert to its previous model of operation. On 10 September 2020, the PR submitted an application to vary the licence to revert the centre's address to the Harley Street site. The PR of centre 0011 has confirmed that there have been no changes to these premises, and they have remained operational for storage under the auspices of the Special Directions.
- 1.5.** The panel noted that the address for the centre will be:
112 Harley Street
London
W1G 7JQ
- 1.6.** The panel noted that that at the time of the desk-based assessment, on 14 September 2020, there were no areas of non-compliance.
- 1.7.** The inspector considered they have sufficient information and evidence to recommend that the application, to revert the centre's premises back to the Harley Street address, be approved.

2. Consideration of application

- 2.1.** The panel considered the papers, which included an executive summary, application form and licensing minutes for the past two years.

- 2.2.** The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.
- 2.3.** The panel noted the inspectorate recommends the approval of the application to reflect a change of existing premises, reverting the centre to its previous address as below:
- 112 Harley Street
London
W1G 7JQ

3. Decision

- 3.1.** The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.
- 3.2.** The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.
- 3.3.** Noting that the dewars, belonging to the centre 0011, had not been moved from the Harley Street address, the panel clarified that, following the endorsement of this variation of premises application, all activity for this centre will only occur at these premises. Any deliveries to the St Thomas Street address would strictly be for use by centre 0070, situated at this address.
- 3.4.** The panel endorsed the inspectorate's recommendation to vary the centre's licence to the following address:
- 112 Harley Street
London
W1G 7JQ

4. Chair's signature

- 4.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Richard Sydee

Date

14 October 2020

Change of premises inspection report



Centre name: The London Sperm Bank

Centre number: 0011

Date licence issued: 1 April 2019

Licence expiry date: 31 March 2022

Additional conditions applied to this licence: None

Date of inspection: 14 September 2020 (desk based assessment)

Inspector: Louise Winstone

Date of Executive Licensing Panel: 7 October 2020

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. Inspections are also carried out when centres apply to vary their licence to change premises. The full inspection prior to a licence being granted, renewed or varied assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an inspection in response to an application from the Person Responsible (PR) to vary the licence to change the centre's premises. The inspection was desk based.

Background

The London Sperm Bank (LSB) has held a storage only licence with the HFEA since 2010, when they took over the former 'Louis Hughes' licensed centre. The centre is part of the London Women's Clinic (LWC) group, under the umbrella of JD Healthcare. The centre is now mainly a storage and distribution centre for donor sperm, providing sperm to clinics within the LWC group, other fertility clinics within the UK and internationally. The centre ceased actively recruiting donors in May 2017 and the donor recruitment for the LWC group moved to The Bridge Centre (centre 0070).

As part of an organisational re-structure within the LWC group, LSB submitted an application on 4 February 2020 to change its licensed premises and relocate to the basement floor of centre 0070. As part of this re-structuring, donor recruitment activities, which had been undertaken by centre 0070 since May 2017, were to revert to centre 0011. This application was approved by ELP on 16 June 2020. Special Directions were also issued to the centre's PR for a period of six months, to authorise gamete storage at the previous premises in Harley Street, so storage dewars could remain there until their relocation to the new premises at The Bridge Centre, anticipating delays as a result of the COVID-19 pandemic.

Following the lifting of COVID-19 restrictions, the centre experienced an unanticipated problem that thwarted their business operating model. Without warning, St Thomas Street, on which the new centre premises are situated, was made a one-way system and a bicycle lane was introduced. This prevents the entry of larger vehicles onto St Thomas Street, including the larger nitrogen delivery vehicles that are needed to deliver the quantity of nitrogen required to serve both centre 0070 and centre 0011 dewars. The PR has confirmed that delivery of smaller quantities of nitrogen required for dewars held by centre 0070 remains uninterrupted due to distant parking and manual filling of transport dewars. The dewars belonging to centre 0011 had not been relocated to the St Thomas Street location and remain at the Harley Street premises.

A decision has been made for centre 0011 to revert to its previous model of operation. On 10 September 2020, the PR therefore submitted an application to vary the licence to revert the centre's address to the Harley Street site. The PR of centre 0011 has confirmed that there have been no changes to these premises, they have remained operational for storage under the auspices of the Special Directions.

LSB imports sperm from Seattle Sperm Bank (SSB) in the United States of America and has an Importing Tissue Establishment (ITE) certificate which authorises this import activity.

Summary and recommendations for the Executive Licensing Panel

The ELP is asked to note that at the time of the inspection there were no areas of non-compliance.

The executive recommends that the application to vary the licence to reflect a change of premises is approved.

The executive notes that the address of the centre will be:

112 Harley Street
London
W1G 7JQ

Details of inspection findings

1. The PR has confirmed that there have been no changes to the premises or equipment at the Harley Street site since the granting of the change of premises variation by ELP in June 2020. Equipment and the cryostore have remained at the Harley Street site under the auspices of the Special Directions (S.D.2020/01/0011/a, expires 21/12/2020) and have been maintained appropriately during the short time, only three months, since the variation was granted. Therefore, it was considered unnecessary to seek key documents from the centre in support of the compliance of this change of premises application. Assurance has already been provided that the premises and equipment at the Harley Street site are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). A site visit was not deemed necessary, however, a desk based assessment was completed, and information provided by the PR in support of the compliance of the centre was subject to desk based assessment.
2. On the basis of this assessment, and as documented below, it was concluded that the centre's proposed premises (the Harley Street site) remain suitable for the conduct of licensed activities because:
 - Confirmation that the premises were designed to meet the requirements of the relevant health technical memoranda and health building notes has previously been provided.
 - Confirmation of the building completion certification/sign off issued by the contractor has previously been provided.
 - Confirmation of a fire safety inspection has previously been provided.
 - Security measures are in place at the premises, including those relating to storage of gametes and confidential records and have previously been considered to be suitable.
 - Documentation confirming that processing of gametes will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality, has previously been reviewed. The PR confirmed that repeat air quality and settle plate monitoring has continued to be performed at the Harley Street premises and will be carried out prior to commencing licensed activities.
 - Confirmation of a deep clean prior to laboratory work starting is not necessary. The PR has confirmed that cleaning of the premises has remained unchanged.
 - Relevant standard operating procedures have been updated to reflect the move back to the Harley Street site.

3. The centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed activities is still present and has remained unchanged since the centre relocation.
4. Testing and re-validation of the dewars and related monitoring alarms is not necessary as they have remained unchanged at the Harley Street site since the centre's last inspection, when they were considered to be compliant with requirements. They have also been monitored and maintained in the usual way during operations under the auspices of the Special Directions.
5. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection on 9 October 2018.
6. The centre has complied with the requirements of General Direction 0008 (section H 14) in submitting:
 - a relevant on-line application form;
 - a floor plan of the premises to be referenced on the licence has previously been provided.

Areas of practice that require the attention of the Person Responsible

This section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

 **'Critical' area of non-compliance**

A 'critical' area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A 'critical' area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None.			

▶ **'Major' area of non-compliance**

A 'major' area of non-compliance is a non critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None.			

▶ **‘Other’ areas of practice that requires improvement**

‘Other’ areas of practice that require improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non-compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None.			

Additional information from the Person Responsible

Dr Ahuja and I have read the report and are happy with the contents of it for submission to the ELP.