Executive Licensing Panel - minutes

Centre 0015 (Sussex Downs Fertility Centre)

Variation of Licensed Premises

Tuesday, 3 September 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Laura Riley Yvonne Akinmodun	Director of Strategy and Corporate Affairs Head of Regulatory Policy Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jeffrey Bowe Dee Knoyle	Licensing Manager Senior Auditor, Government Internal Audit Agency Committee Officer

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 Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a treatment and storage licence with the HFEA since 1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex and provides a full range of fertility services.

1.2. The panel noted that in the 12 months to 30 April 2019, the centre had provided approximately 400 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.3. The panel noted that an interim inspection was conducted on 13 February 2018, during which one major and four 'other' areas of non-compliance or poor practice were noted. The Executive Licensing Panel (ELP) considered the inspection report on 25 April 2018 and was satisfied the centre was fit to have its treatment and storage licence continued.

1.4. The panel noted that on 1 May 2019, the Person Responsible (PR) informed the executive of an imminent change in ownership of the centre and of the new owner's plans to relocate the centre to new premises in a few months' time. As part of the prelude to this move and due to the decommissioning of some areas of the main BMI Esperance hospital, the centre's offices, patients' records store, production room and two scanning/consulting rooms are to be relocated within the hospital building to existing rooms on the ground floor which are not considered to be licensed at present. This additional area of rooms also provides additional bedrooms for patients.

1.5. The PR submitted a licence variation application on 7 August 2019 to vary the centre's licence to incorporate the additional area of rooms into the centre's licensed premises.

1.6. The panel noted that the executive considered that the activities to be undertaken within the proposed additional premises are necessary to support the provision of licensed treatment activities, but are not themselves licensable. As such, the executive considered an on-site inspection of the proposed additional premises to be unnecessary and that a desk-based assessment would be proportionate.

1.7. The panel noted that a desk-based assessment was conducted on 8 August 2019 and there were no aspects of practice that required improvement.

1.8. The panel noted that the inspection team considered that there is sufficient information available to recommend the variation of this centre's licence, without additional conditions, to incorporate the additional area of rooms into the centre's licensed premises.

2. Consideration of application

2.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past three 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 that the inspectorate recommends the approval of the variation of the centre's licence to incorporate the additional area of rooms into the centre's licensed premises.

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. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. The panel noted that there were no aspects of practice that required improvement.

3.5. The panel endorsed the inspectorate's recommendation to approve the variation of the centre's licence, without additional conditions, to incorporate the additional area of rooms into the centre's licensed premises.

4. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

6 September 2019

Change of premises report

Centre name: Sussex Downs Fertility Centre
Centre number: 0015
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of desk-based assessment: 8 August 2019
Inspector: Sandrine Oakes
Date of Executive Licensing Panel: 3 September 2019

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. The inspection prior to a licence being granted or renewed assesses a centre's compliance with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This report relates to an application to vary the current licensed premises and documents a desk-based assessment of information provided by the centre in support of the application. An onsite inspection was not required or considered necessary given the nature of the changes made. The desk-based assessment reviewed the suitability of the centre's changed premises against HFEA CoP and SLC requirements. The report is used to inform the HFEA licensing panel which will decide whether to approve the licence variation application.

Background

The Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a Treatment and Storage licence with the HFEA since 1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex.

The centre provides a full range of fertility services.

The centre provided approximately 400 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a small centre.

The last inspection of the centre was an interim inspection on 13 February 2018, during which one major and four 'other' areas of non-compliance or poor practice were noted. The ELP considered the inspection report on 25 April 2018. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

On 31 May 2019, the PR informed the executive of an imminent change in ownership of the centre and of the new owner's plans to relocate the centre to new premises in a few months' time. As part of the prelude to this move and due to the decommissioning of some areas of the main BMI Esperance hospital, the centre's offices, patients' records store, production room and two scanning/consulting rooms are to be relocated within the hospital building to existing rooms on the ground floor which are not considered to be licensed at present. This additional area of rooms also provides additional bedrooms for patients. The PR therefore applied on 7 August 2019 to vary the centre's licence to incorporate this additional area of rooms into the centre's licensed premises.

The executive considered that the activities to be undertaken within the proposed additional premises are necessary to support the provision of licensed treatment activities but are not themselves licensable. As such, the executive considered an on site inspection of the proposed additional premises to be unnecessary and that a desk-based assessment would be proportionate. This report describes the findings of that assessment.

Summary for the Executive Licensing Panel

The ELP is asked to note that at the time of the desk-based assessment there were no aspects of practice that required improvement.

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

Details of inspection findings

1. Key documents were requested from the centre in support of the application, to provide assurance that the proposed additional premises are suitable and satisfy the legal requirements in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). On the basis of the assessment of these documents, and as described below, it is concluded that the centre's proposed additional premises are suitable for the conduct of licensed activities.

2. In essence, the centre proposes to add several rooms on the ground floor of the hospital to the centre's licensed premises, to provide three offices (one with secure patient records storage facilities), a waiting area for patients, two consulting/scanning rooms, a room for men to produce sperm samples, and up to five patient bedrooms. The PR has confirmed that no licensed treatment will be conducted in the proposed consulting/scanning rooms and that the bedrooms are for the use of patients prior to procedures and when they have been released from the centre's procedure room after their procedure and recovery. The PR has confirmed that their process for transferring patients from the procedure room to their bedroom has been considered from a patient safety perspective. A dedicated nursing team is responsible for patients on the ward before they are discharged home.

3. The proposed additional premises are existing rooms on the ground floor of the hospital which are not considered to be licensed at present but are situated one floor above the licensed premises. The proposed additional premises are in the same building as the current licensed premises, therefore it is lawful for them to be added to the premises authorised by the centre's licence, should the panel choose to approve this application.

4. The PR has confirmed there has been no major building works and as such a building completion certification was not necessary.

5. The PR has confirmed that the centre's current premises will continue to be used for all licensed activity, providing the centre's laboratories, storage facilities and procedure room/recovery area. Insemination treatments will be carried out in the procedure room which is already licensed, and not in the proposed consulting/scanning rooms as was originally considered.

6. The current premises will not be affected by the proposed changes.

7. The PR has conducted and provided a self-assessment of the compliance of the proposed additional premises with HFEA requirements. The PR has confirmed that the proposed additional premises offer suitable facilities to carry out the activities to be undertaken there. This self-assessment incorporated consideration of infection control and medicines management. It is noted that some of the rooms in the proposed additional premises are existing clinical areas and meet infection control requirements relevant to the activities to be undertaken within them.

8. Electrical and fire safety testing and risk assessment have been carried out within the proposed additional premises and the premises are considered safe for the activities to be undertaken there.

9. The PR has provided assurance that the rooms are lockable and that appropriate security arrangements are in place to maintain the confidentiality of patient records and other centre documentation.

10. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in 2016, then at the interim inspection in February 2018. The centre does not intend to change any activities or the licence type. The PR has provided assurance that relevant standard operating procedures and other documents in the quality management system have been updated to reflect the change in premises.

11. The centre has complied with the requirements of General Direction 0008 (Section H 13) in submitting:
    - a relevant on-line application form;
    - a floor plan of the premises to be referenced on the licence.

Recommendation

The executive recommends that the panel approves this application to vary the licence provided to centre 0015, to add the additional rooms on the ground floor of the hospital to the centre's licensed premises.

Areas of practice that require the attention of the Person Responsible

The 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

Areas of practice that requires 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