Executive Licensing Panel Minutes

Centre 0322 (Brighton Fertility Associates)

Variation of Licenced Premises

Date:	23 March 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Anna Coundley	Director of Strategy and Corporate Affairs Communications Manager Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood India Hickey	Licensing Manager Research 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 Brighton Fertility Associates has been licensed by the HFEA since 2012. The centre provides basic fertility services and the storage of gametes, including donor sperm.

1.2. The panel noted that, in the 12 months to January 2021, the centre had provided 6 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a small sized centre.

1.3. The panel noted that the centre was last inspected on 21 August 2019, when an interim inspection was performed. At the time of this inspection, there were no areas of practice that required improvement.

1.4. The Person Responsible (PR) submitted a licence variation application on 25 October 2020 to change the address of the licenced premises to the following address:

15 Boundary Road
Hove
East Sussex
BN3 4EF

1.5. The panel noted that, due to the Covid-19 pandemic, a desk based assessment (DBA) and risk based approach (RBA) was taken for this change of premises application. Following the DBA/RBA for this centre, it was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively via teleconference rather than on-site inspection; the DBA included several teleconference meetings with the centre's PR. This approach removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.6. The panel noted that a standard renewal inspection is due to be conducted at the centre in Summer/Autumn 2021 and this will include a review of the new 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 five years.

2.2. The panel noted that, at the time of the of the DBA/RBA, conducted in March 2021, there were two major areas of non-compliance, concerning suitability of premises and equipment. There was also one 'other' area of non-compliance regarding staff. The PR has committed to implementing all the recommendations made in the report before commencing licensed treatments.

2.3. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

2.4. The panel noted that the inspectorate recommends the approval of the application to vary the licence to reflect the change of premises to the following address, subject to the recommendations in the report being implemented:

15 Boundary Road
Hove
East Sussex
BN3 4EF

2.5. The panel noted that, assuming this application is approved, there will be a period of time after the licence variation, when the centre will need to store gametes and medical records at the centre's old premises (Lower Ground Floor, Olivier House, 18 Marine Parade, Brighton, East Sussex, BN2 1TL).The PR has requested a Special Direction, to be in force from the date the licence is varied, for three months; this will allow storage of gametes and medical records to be kept at the old premises, until they are moved to the new premises. The executive considered the storage facilities at the old premises to be suitable at the last inspection, noting that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. It is recommended that this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended), is approved.

2.6. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) importing certificate, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. If this application is approved the centre's ITE certificate should be amended to reflect the new address of the centre.

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 endorsed the inspectorate's recommendation to change the centre's licensed premises, subject to the recommendations made in the report being implemented, to:

15 Boundary Road
Hove
East Sussex
BN3 4EF

3.5. The panel endorsed the inspectorates recommendation to issue a Special Direction, for a period of three months, from when the licence variation is implemented, to enable gametes and medical records to be stored at the centre's old premises at Lower Ground Floor, Olivier House, 18 Marine Parade, Brighton, East Sussex, BN2 1TL.

3.6. The panel agreed that the centre's ITE import certificate should be amended to reflect the centres change of premises.

4. Chairs signature

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

Signature

Name

Clare Ettinghausen

Date

24 March 2021

Change of Premises Inspection Report

Centre name: Brighton Fertility Associates
Centre number: 0322
Date licence issued: 20 February 2018
Licence expiry date: 19 February 2022
Additional conditions applied to this licence: None
Date of desk based assessment: March 2021
Inspectors: Bernadette O'Leary (Lead), Sara Parlett
Date of Executive Licensing Panel: 23 March 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). 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 a change of premises inspection.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

Following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively via teleconference rather than on-site inspection. This removed the risks to patients and staff,

associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by desk based assessment, which included several teleconference meetings with the centre's Person Responsible (PR) at various points throughout the inspection process.

The executive also notes that a standard renewal inspection is due at the clinic in the summer/autumn of 2021, which will include a review of the new premises.

Background

Brighton Fertility Associates has been licensed by the HFEA since 2012. The centre provides basic fertility services and the storage of gametes including donor sperm.

The centre provided six cycles of treatment (excluding partner intrauterine insemination) in the 12 months to January 2021. In relation to activity levels this is a very small centre.

The centre was last inspected on 21 August 2019 when an interim inspection was performed. At the time of inspection there were no areas of practice that required improvement.

The centre submitted an application on 25 October 2020 to vary its licensed premises to relocate to new premises. The rationale for this is to save financially on service charges and rent so that more can be invested in the business. The new premises also provides better parking access for patients, donors, and couriers.

Summary and recommendations for the Executive Licensing Panel

The Executive Licensing Panel (ELP) is asked to note that at the time of the inspection there were three areas of practice that required additional work.

The PR has committed to implementing the following recommendations before commencing licensed treatments:

Major areas of non-compliance:

- The PR must not commence licenced treatment until they have provided evidence that the proposed new premises are suitable for conduct of licensed treatments.
- The PR must not commence licensed treatment until all validation of equipment and the cryostore alarm system has been performed.

'Other' areas of non-compliance:

- The PR must ensure that all staff have taken part in an induction process for the new premises.

The executive recommends that the application to vary the licence to reflect a change of premises is approved subject to the recommendations made in this report being implemented.

The executive notes that the new address of the centre will be:
15 Boundary Road
Hove
East Sussex
BN3 4EF

Assuming the ELP approve this application, there will be a period of time after the licence is varied when the centre will need to store gametes at the centre's 'old' premises (Lower Ground Floor, Olivier House, 18 Marine Parade, Brighton, East Sussex, BN2 1TL). A Special Direction has therefore been requested by the PR to be in force from the date the licence is varied for three months following variation of the centre's licence, to allow storage of gametes and medical records at the 'old' premises until they are moved to the new premises. The executive considered the storage facilities at the 'old' premises to be suitable at the last inspection and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. It is recommended therefore that the ELP approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

The centre has been issued with an Importing Tissue Establishment (ITE) importing certificate, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. If this application is approved the centre's ITE certificate should be amended to reflect the new address of the centre.

Details of Inspection findings

1. Key documents were requested from the centre in support of the change of premises application assessment, to provide assurance that the premises and equipment in the proposed new facilities 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)). On

completion of the desk based assessment a final teleconference with the PR was held on 10 March 2021. On the basis of these assessments, and as documented below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

- Confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided.
- Confirmation that planning permission or building regulations approval is not required for these alterations has been provided by the PR.
- Confirmation of a fire safety inspection was provided.
- A revised SAQ to demonstrate compliance with General Direction 0014 (version 2) at the new premises has been provided and was considered suitable.
- Security measures in place at the new premises, including those relating to storage of gametes and confidential records were considered to be suitable.
- Evidence that background air quality of Grade D has been achieved in the laboratory has been provided. Testing to demonstrate that processing of gametes will take place in an environment of at least Grace C air quality remains to be performed. The PR confirmed that air quality and settle plate monitoring will be carried out prior to commencing licensed activities in the new premises (see recommendation 1A).
- Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated consultation & treatment and male production rooms are available and appear fit for purpose.
- Confirmation of a deep clean prior to laboratory work starting will be provided prior to licensed treatment commencing (see recommendation 1B).
- Confirmation that all relevant SOPs have been updated to reflect physical differences in premises, where relevant, has been provided.

2. The laboratory and clinical equipment sufficient to be able to perform licensed treatment have not yet been validated and/or calibrated for use in the new premises. Confirmation of these will be provided prior to licensed treatment commencing (see recommendation 2A).

3. Testing and re-validation of the dewars and related monitoring alarms cannot be undertaken by the centre until they have been transferred from the current to the new premises (see recommendation 2B).

4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection on 15 August 2017. The centre does not intend to change any activities or the type of licence.

5. Following the move, and prior to licensed activity commencing at the new premises, the PR has agreed to confirm the following;
   - air quality testing has been repeated and meets the required standard.
   - a final deep clean has been undertaken.
   - validation of all critical equipment has been performed, including testing and re-validation of the dewars and the associated alarms has been undertaken.
   - a staff induction process has taken place for all staff (see recommendation 3).

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.

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
1. Suitability of Premises Once all equipment and furnishings have been moved into the new premises, and before licensed activity commences the following will be required: A. Confirmation that processing of gametes and embryos will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality. SLC T20.	The PR must not commence licensed treatments until evidence has been provided that the proposed new premises are suitable for conduct of licensed treatments. Before licensed activity commences, the PR should provide confirmation to the centre’s inspector that: A. The laboratory air quality is compliant with SLC T20. B. A final deep clean has taken place.	Agree to all proposals	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

B. Confirmation that a deep clean has taken place. SLC T17.			
2. Equipment Once all equipment and furnishings have been moved into the new premises, and before licensed activity commences the following will be required: A. The laboratory and clinical equipment sufficient to be able to perform licensed treatment have not been validated and/or calibrated for use in the new premises. SLCs T17, T24 and General Direction 0008. B. Testing and re-validation of the dewars and related monitoring alarms should be undertaken by the centre once they have been transferred from the	The PR must not commence licensed treatments until evidence has been provided that the proposed equipment is suitable for conduct of licensed treatments. Before licensed activity commences, the PR should provide confirmation to the centre's inspector that: A. The laboratory and clinical equipment have been validated and/or calibrated. A sample of validation documents may be requested for review by the executive. B. The dewars and associated monitoring alarm systems have been tested and validated once they have been moved to the new premises.	Agree to all proposals.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

current to the new premises. SLCs T17, T24 and general Direction 0008.	Evidence of this validation should be provided.		

‘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
3. Staff At the time of the assessment, an induction to the new premises had not yet taken place for all staff. SLC T15.	The PR must ensure that all staff have taken part in an induction process for the new premises. The PR should provide confirmation to the centre’s inspector that a staff induction process has taken place for all staff, which must be before licensed activity commences.	All staff have had initial orientation to the new premises. I will provide all staff inductions when we are at the new premises, along with individualised Health and Safety Assessments eg workstation DSE assessments for use of work areas in new surroundings.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

Additional information from the Person Responsible
I would greatly appreciate the committees help so that the transfer of our treatment and storage licence can be expedited as soon as possible so we can move our clinical notes and storage dewars to the new location immediately. We have been under severe financial pressure due to the COVID playing havoc with any planning we have done. The new unit is secure and licence - appropriate for clients as far as I can make it already but we need the transfer of licence for legal storage of the notes and dewars. Thank you for your consideration of this matter. Suzy Duffy PR