Executive Licensing Panel - minutes

Centre 0254 (The Agora Gynaecology and Fertility Centre)

Variation of Licensed Premises

Tuesday, 17 November 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Dan Howard Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Chief Information Officer Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Jane Darragh	Licensing Manager Research Manager (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 Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has been licensed with the HFEA since 2007. The centre provides a full range of fertility services, including the storage of gametes and embryos.

1.2. The panel noted that, on 29 September 2020, a variation of licensed premises application was made by the Person Responsible (PR), to establish a new larger cryostorage area within the same premises, to support the need for more storage of cryopreserved samples. The PR had intended to submit the application last year, but plans were put on hold due to the Covid-19 pandemic.

1.3. The panel noted that an interim inspection was conducted at the centre on 20 August 2019. Recommendations were made to address two major non-compliances and the PR has provided evidence that these have been implemented. During this inspection, the proposed larger cryostorage room had been assessed and considered suitable for the purpose proposed at that time.

1.4. The panel noted that at the time of the desk-based assessment, on 15 October 2020, there were no areas of non-compliance. The PR has provided written confirmation that if this application is approved, the dewars and monitoring systems will be re-validated once they have been moved to the new room.

1.5. The inspector considered they have sufficient information available to recommend the variation of this centre's licence to relocate the current cryostorage room to the proposed larger room (as noted on the clinic's floorplan) within the same premises, without additional conditions.

2. Consideration of application

2.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past four 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, to relocate the current cryostorage room to the proposed larger room (as noted on the clinic's floorplan) within the same premises, without additional conditions.

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.

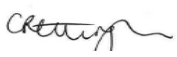
3.2. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.3. The panel endorsed the inspectorate's recommendation to approve the application, to reflect a change of existing premises, to relocate the current cryostorage room to the proposed larger room (as noted on the clinic's floorplan) within the same premises, without additional conditions.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

23 November 2020

Licence Variation Application Report

Inspectors: Polly Todd and Louise Winstone

Date of assessment: 15 October 2020

Date of Executive Licensing Panel: 17 November 2020

Purpose of report: Desk-based assessment of the centre's application to vary its licence to relocate its current cryostorage room to another larger room within the same premises.

Centre details

Centre name	The Agora Gynaecology and Fertility Centre
Centre number	0254
Licence number	L/0254/6/b
Centre address	The Agora, Ellen Street, Brighton and Hove, BN3 3LN
Person Responsible	Dr Carole Gilling-Smith
Licence Holder	George Koustas
Date licence issued	01 February 2018
Licence expiry date	31 January 2022
Additional conditions applied to this licence	None

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Agora Gynaecology and Fertility Centre is located in Brighton and Hove and has been licensed with the HFEA since 2007. The centre provides a full range of fertility services including the storage of gametes and embryos.

The centre provided 874 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2020. In relation to activity levels this is a medium centre.

The centre was last inspected on 20 August 2019 when an interim inspection was performed. Recommendations were made to address two major non compliances. The PR has provided evidence that these recommendations have been implemented.

A variation of the licence to change the Licence Holder was approved on 3 October 2019.

The centre submitted an application on 29 September 2020 to vary its licensed premises to establish a new larger cryostorage area within the same premises, to support the need for more storage of cryopreserved samples. The PR had intended to submit the application last year but plans to do so were put on hold due to the Covid-19 pandemic.

Summary for licensing decision

In considering overall compliance, the inspectors consider that they have sufficient information drawn from documentation submitted by the centre to conclude that:

- The proposed cryostore room was reviewed at the last inspection and deemed to be suitable for the proposed purpose.
- The practices to be used for storing gametes and embryos are suitable.
- The centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licence.

The Executive Licensing Panel is asked to note that there are no areas of practice that require improvement. The PR has provided written confirmation that if this application is approved, the dewars and monitoring systems will be re-validated once they have been moved to the new room.

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the variation of this centre's licence to relocate the current cryostorage room to the proposed larger room (as noted on the clinic's floorplan) within the same premises, without additional conditions.

Details of assessment findings

The licence variation application

An application has been received from the PR at centre 0254 to vary the centre's licence to move the existing cryostore room to a larger room within the same premises. The new larger room is located on the same floor as the existing cryostore and will provide space for more cryostorage tanks in the centre.

The applicant has complied with all the requirements of General Direction 0008 (paragraph 14) in submitting the following:

- an application form signed by the PR;
- a copy of the clinic's floorplan to be referenced on the licence;
- confirmation that any relevant equipment has been tested and will be validated in the new location.

Desk-based assessment of the application

The application for a variation of the centre's licence to move the existing cryostore to a larger room within the premises was considered by a desk based assessment. This was because the proposed larger room had been reviewed at the last inspection in August 2019 and was considered suitable for the purpose proposed at that time. Relevant documents submitted by the PR with this application have been reviewed against the requirements of the Human Fertilisation and Embryology Act 1990 (as amended), General Directions, Standard Licence Conditions (SLCs) and the Code of Practice (CoP).

On the basis of these assessments, it was concluded that the centre's proposed new cryostorage room is suitable for the conduct of licensed activities for the following reasons:

- The proposed cryostore is within the centre, so it is lawful to add the proposed cryostore to the premises authorised by the centre's licence. A floor plan has been provided detailing the room's location.

- The room is under the control of the PR, is secure and evidence has been provided that access to it is limited to specific members of the laboratory team authorised by the PR.

- A fire safety inspection has been performed and has confirmed the room to be safe.

- A thorough clean of the cryostore is planned and will be repeated once the licence has been varied and existing cryostore equipment is relocated to the new premises.

- The room has been fitted with appropriate safety signage.

- The room has been equipped with an appropriate oxygen monitoring system, with displays and alarms inside and outside the room, and a boosted extraction system to clear any nitrogen spillages. A completion certificate and validation of the oxygen monitoring system has been issued. Further validation will be performed after all cryostore equipment has been relocated.

- The PR has outlined plans to re-validate dewars and their monitoring devices when they are transferred from the old to the new cryostorage room, assuming the licence variation is approved. This work will be undertaken as part of normal activity compliant with the centre's standard licence conditions.

- The centre's critical processes related to cryopreservation are not affected by the addition of this new cryostore to the licensed premises and were considered appropriate at the time of the last inspection in August 2019.

- The PR has provided evidence which confirms that standard operating procedures (SOPs) relevant to the new cryostore have been reviewed and revised where necessary. The documents are considered suitable.

- The new cryostore has been risk assessed, as have the activities to be undertaken within it, and the movement of stored material between it and the centre's laboratory.

- Staff with access to the new cryostorage room have had appropriate induction and training to allow them to use the room safely.

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 to a 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	Executive Review
None identified			

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 to a 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	Executive Review
None identified			

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	Executive Review
None identified			

Additional information from the Person Responsible
The fire risk assessment is now complete. Action points have been addressed.