Executive Licensing Panel - minutes

Centre 0105 (London Women's Clinic)

Variation of Licensed Premises

Tuesday, 21 April 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Kathleen Sarsfield Watson Niamh Marren	Director of Finance and Resources Communications Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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 Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services, including embryo testing to self-funded patients. LWC is part of a nationwide group of centres and has several satellite and transport centres.

1.2. The panel noted that in the 12 months to December 2019, the centre had provided 2901 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is large sized centre.

1.3. The panel noted that the centre's licence was last renewed in 2018, for a period of three years. Following a grade 'A' incident in 2012, an additional condition was imposed on the centre's licence and remains in place. This condition suspended the centre (and other centres within the LWC group) using donor sperm procured, processed and stored at the centre prior to the introduction of the electronic witnessing system in May 2010.

1.4. The panel noted that following an interim inspection on 29 January 2019, recommendations for improvement were made in relation to three major areas of non-compliance or poor practice. The Person Responsible (PR) has provided information and evidence that all the recommendations were fully implemented within the required timescales.

1.5. The panel noted that in October 2019, a variation of licensed premises application was submitted by the PR. The centre needs to relocate its andrology laboratory and remove a partition wall within the room used as a cryo-store, increasing the size of the room to allow for greater capacity. The executive has performed an on-site inspection of these rooms and the report provides a summary of evidence for its compliance and suitability for licensing.

1.6. The panel noted that a site visit was conducted on 18 February 2020. Relevant documents were reviewed on site, and then on 21 and 24 February 2020, having been forwarded by the PR to the inspector. On the basis of these assessments, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

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 the inspectorate recommends the approval of the application to permit the change of use of an area previously used as an office, to be used for an andrology laboratory, and for the room used for storing gametes and embryos to continue to do so with its amendments.

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 vary the centre's licence to reflect a change of existing premises to permit the change of use of an area previously used as an office, to be used for an andrology laboratory, and for the room used for storing gametes and embryos to continue to do so with its amendments.

4. Chair's signature

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

Signature

Name

Richard Sydee

Date

29 April 2020

Licence Variation Application Report

Inspectors: Victoria Brown and Andrew Leonard
Date of inspection: 18 February 2020
Date of Executive Licensing Panel: 21 April 2020
Purpose of report: Assessment of the centre's application to vary its licence to relocate its andrology laboratory and increase the size of the room used as a cryo-store.

Centre details

Centre name	London Women's Clinic
Centre number	0105
Licence number	L/0105/20/a
Centre address	113-115, Harley Street, London, W1G 6AP, United Kingdom
Person Responsible	Mrs Tourandokht Arian-Schad
Licence Holder	Dr Kamal Ahuja
Date licence issued	29 March 2018
Licence expiry date	28 March 2021
Additional conditions applied to this licence	To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The London Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to self-funded patients. LWC is part of a nationwide group of centres and has several satellite and transport centres.

The centre provided 2901 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2019. In relation to activity levels this is a large centre.

The centre's licence was last renewed in 2018, for a period of three years. Following a grade 'A' incident in 2012, an additional condition was imposed on the centre's licence and remains in place. This condition suspended the centre (and other centres within the LWC group) using donor sperm procured, processed and stored at the centre prior to the introduction of the electronic witnessing system in May 2010.

Following an interim inspection on 29 January 2019, recommendations for improvement were made in relation to three major areas of non-compliance or poor practice.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales.

An application has been submitted by the PR at centre 0105 to vary the centre's licence to relocate its andrology laboratory and to remove a partition wall within the room used as a cryo-store, increase the size of the room to allow for increased capacity. The executive has performed an on-site inspection of these rooms and this report provides a summary of evidence for its compliance and suitability for licensing.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from the on-site inspection and documentation submitted by the centre to conclude that:

- the rooms are suitable to be used as an andrology laboratory and the cryo-storage facility is suitable for storing gametes and embryos;
- the practices to be used for andrology services and storing gametes and embryos are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises.

The Executive Licensing Panel is asked to note that at the time of the inspection there are no areas of non-compliance requiring improvement.

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 with the existing condition, to permit the change of use of an area previously used as an office, to be used for an andrology

laboratory, and for the room used for storing gametes and embryos to continue to do so with its amendments.

Details of assessment findings

The licence variation application

An application was submitted by the PR on 21 October 2019 to vary the centre's licence to relocate the centre's andrology laboratory and to make amendments to the existing cryo-storage room within the licensed premises. An area that was previously used as an office has been converted into an andrology laboratory and a partition wall has been removed from the cryo-storage room to facilitate space for more dewars.

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

- an application form;
- a floor plan showing the amendments

Details of the inspection findings

Key documents were requested from the centre in support of the change of premises application, 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)).

A site visit was conducted on 18 February 2020. Relevant documents were also reviewed on site and later on 21 and 24 February 2020 having been forwarded by the PR to the inspector.

On the basis of these assessments it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

- The proposed cryostore and andrology laboratory are within the area within the premises authorised by the centre's licence. A floor plan has been provided detailing the location of the rooms.

- The rooms are under the control of the PR, are secure and access to them is limited to specific members of the laboratory team authorised by the PR.

- The rooms have been refurbished to meet the requirements of the relevant health technical memoranda and health building notes. The andrology laboratory has fully washable walls and surfaces, flooring that curves to the wall and has an air filtration system. The cryo-store 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.

- A deep clean of the rooms has been carried out and evidence has been provided to the centre's inspector.

- The rooms have been fitted with appropriate safety signage.

- The andrology laboratory has a refrigerator, a warming incubator, seven centrifuges and two microscopes. The cryo-store has a large number of dewars and liquid nitrogen is piped directly into the room via two points. All equipment has been installed and validated. The incubator, refrigerator and dewars are monitored by the laboratory monitoring system.

- The centre's critical processes related to cryopreservation and andrology are not affected by the changes made to these rooms within the licensed premises and were considered appropriate at the time of the last renewal inspection in October 2017 and the interim inspection in January 2019.

- The PR has advised that standard operating procedures (SOPs) relevant to the new cryostore and andrology laboratory are unchanged by the refurbishment.

- The andrology laboratory and cryostore have been risk assessed, as have the activities to be undertaken within them. The rooms have been confirmed to be safe.

- Staff with access to these rooms have had appropriate induction and training to allow them to use the rooms and equipment contained within safely.

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 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 require 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	Executive Review
None identified			

Additional information from the Person Responsible