Executive Licensing Panel - minutes

Centre 0105 (London Women's Clinic) Variation of Licensed Premises

Friday, 26 February 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Nick Jones Anna Rajakumar	Director of Strategy & Corporate Affairs Director of Compliance & Information Scientific Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The London Women's Clinic, centre 0105, is part of a nationwide group of centres and has several satellite centres. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing.

1.2. In the 12 months to 30 September 2015, the centre provided 2581 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.3. The panel noted that centre 0105 currently has an additional condition on its licence. The condition is to suspend the centre using donor sperm following a grade 'A' incident in 2012 (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.

1.4. On 4 November 2015 the Person Responsible (PR) applied to vary the centre's licence to reflect a change of premises. A new laboratory was created within the treatment suite, this was previously a waiting area which was refurbished.

2. Consideration of application

2.1. The panel considered the papers, which included a completed application form, a report and licensing minutes for the past three years.

2.2. The panel noted that the PR confirmed that staff, protocols, equipment, consumables and practice will remain unchanged. The PR has stated in the application form that the centre is planning to use this section of the laboratory suite for 100 embryo biopsy procedures and 800 IVF/FET/ICSI procedures per year.

2.3. The panel noted that key documents were submitted by the centre in support of the application, to provide assurance that the premises and equipment therein 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 was concluded that the centre's proposed new laboratory area is suitable for the conduct of licensed activities.

2.4. The panel noted that the PR confirmed that there were no major building works carried out. A stud wall was erected to divide an existing room, and as such, building completion certification was not necessary.

2.5. The panel noted that electrical testing has been carried out and the certificate has been provided in evidence of electrical safety.

2.6. The panel noted that confirmation of an effective deep clean of the laboratory area has been provided, including air quality monitoring and microbiology reports.

2.7. The panel noted that the centre has purchased some new equipment for the laboratory including airflow hoods and nitrogen storage dewars. The dewars are to be stored in the existing storage facility. The PR has provided evidence to confirm that new equipment has been validated and that recommissioned equipment has been tested and validated. The inspector considers that the centre has suitable validated equipment to perform the licensed activities.

2.8. The panel noted that the centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in October 2013, then at the interim inspection in October 2015. The centre does not intend to change any activities or the licence type. Relevant standard operating procedures and other documents in the quality management system have been updated to reflect the change in premises.

2.9. The panel noted that at the time of the desk-based assessment, there were no aspects of practice relating to the premises that required improvement.

2.10. 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.

2.11. The panel noted that the inspectorate recommends the variation of the centre's licence to reflect a change of premises.

3. Decision

3.1. The panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13).

3.2. The panel endorsed the inspectorate's recommendation to vary the centre's licence to reflect a change of premises with immediate effect.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

10 March 2016