

HFEA Executive Licensing Panel Meeting

10 August 2012

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

Minutes – Item 3

Centre 0301 – (London Women’s Clinic, Cardiff) – Variation of Licence to change the licensed premises, change the centre’s name and change the type of licence to treatment and storage.

Members of the Panel: Juliet Tizzard, Head of Policy & Communications (Chair) Danielle Hamm, Senior Policy Manager David Moysen, Head of Information Technology	Committee Secretary: Joanne McAlpine
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Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre has been licensed by the HFEA since 2008 for intrauterine insemination, donor insemination and storage of sperm. The centre's current licence is valid until 29 February 2016.
2. The Panel noted that the centre also operates as a satellite centre for other HFEA licensed centres within the London Women's Group (centres 0059 and 0105).
3. The Panel noted that the Person Responsible (PR) has applied to vary the centre's current licence:
 - to re-locate the HFEA licensed premises to 15 Windsor Place, Cardiff, CF10 3BY;
 - to re-name the centre to be London Women's Clinic, Wales; and
 - to change the licence type from Treatment (insemination using partner/donor sperm) and Storage to Treatment and Storage.
4. The Panel noted that the PR has stated that the practices used at centre 0059 are to be used at centre 0301 for the additional activities introduced by the licence variation and that the staff, quality management system, equipment, processes and practices from centre 0059 are being merged into the new premises.
5. The Panel noted that the PR and Quality Manager demonstrated on the inspection to the satisfaction of the Inspectorate that the components listed above are compliant with the Code of Practice requirements.
6. The Panel noted that on-going monitoring of recommendations in the previous inspection report indicates that no actions to correct non-compliances at either centre remain outstanding.
7. The Panel noted that a detailed plan has been developed for the transfer of stored gametes and embryos, equipment, furniture and other material from centres 0059 and 0301 to the new location for centre 0301. This includes risk assessments for all aspects of the movement of critical material and equipment.
8. The Panel noted that at the time this inspection took place for the change of premises there were two areas of practice that required improvement relating to the revalidation of the critical equipment and that the testing of air quality. The Inspectorate recommended that these recommendations be addressed before the commencement of licensable activities.
9. The Panel noted that the centre has submitted documents in accordance with HFEA General Directions 0008.

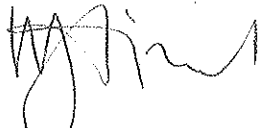
10. The Panel noted the Inspectorate's recommendation to vary the centre's licence subject to compliance with the recommendations made in the report being implemented within the prescribed timeframes.

Decision

11. The Panel agreed to the Inspectorate's recommendation to vary the centre's licence to change its name to 'London Women's Clinic, Wales'.
12. The Panel agreed to the Inspectorate's recommendation to the relocation of the centre's premises to 15 Windsor Place, Cardiff.
13. The Panel agreed to the Inspectorate's recommendation to vary the centre's licence to Treatment and Storage.
14. The Panel would like to remind the PR that licensed treatments must not commence until a sample of the revalidation documents and the air quality test results have been submitted to the HFEA and that the Inspectorate is satisfied that they meet the relevant requirements.
15. The Panel would like the Inspectorate to carry out on-going monitoring after the commencement of licensable activities to ensure that activity is running as expected.

Signed:

Date:



20/8/12

Juliet Tizzard (Chair)

