

HFEA Executive Licence Panel Meeting

17 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0289 (The North Middlesex University Hospital Fertility Unit) – Variation of licence for change of centre name and change of premises

Members of the Panel: Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett – Director of Finance & Facilities	Committee Secretary: Joanne McAlpine
--	---

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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included an application for the variation of premises and centre name, an executive summary and previous minutes of the previous Licence Committees.
2. The Panel noted that the centre is part of the North Middlesex Hospital NHS Trust and has been licensed by the HFEA since July 2007. However, the Panel noted that due to resourcing issues, licensed treatments did not commence until September 2009.
3. The Panel noted the licensing history of the centre, and in particular noted that in June 2010 the Person Responsible (PR) informed the HFEA that licensed treatments had been stopped, due to the building being demolished as part of a Trust development plan and that the centre was to relocate to another part of the Trust site.
4. The Panel noted that the appropriate applications forms and supporting documentation had been submitted, and that the Inspectorate are satisfied that it meets the requirement set out in Direction 0008.
5. The Panel noted that the Inspector for this centre has visited the centre twice previously, most recently in February 2010.
6. The Panel noted that the actions required at the last inspection are being addressed by the centre staff and the inspector for the centre is in close contact with the PR regarding these.
7. The Panel noted that the air quality assessment results have been submitted for the new premises, where the processing of gametes and embryos exposes them to the environment, and the Inspectorate have stated that the results show that processing will take place in an environment of at least Grade A air quality.
8. The Panel noted that the new equipment has been commissioned and tested, in accordance with standard licence condition T25.
9. The Panel noted the Inspectorate's recommendation to vary the centre's licence to reflect the change of centre name and the change of premises, subject to the centre complying with a number of recommendations.
10. The Panel noted that the centre has applied to vary its name to North Middlesex University Hospital (Reproductive Medicine Unit).

Decision

11. The Panel agreed to the variation of licence for the change of premises and the variation of the centre name as stated in paragraph 10, in accordance with section 18A of the HFE Act.
12. The Panel endorsed the Inspectorate's recommendations and would ask the PR to ensure that the following are complied with before licensed activity commences at these premises:
 - The equipment in use at the previous premises has been re-commissioned, tested and validated before use. (Standard Licence Condition T25).
 - The new equipment has been validated (Standard licence condition T25).
 - The air quality in the laboratory gamete/embryo processing area and procedures rooms has been re-tested and meets, at least, Grade C with Grade D background, before commencing licensed activity.

Signed:



Date:

3/12/10.

Peter Thompson (Chair)

