

HFEA Executive Licensing Panel Meeting

6 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 10

IVF Wales (0049) - Application to vary to change the licensed research premises and provide the centre with a new HFEA number – (R0161)

Members of the Panel:

Mark Bennett, Director of Finance & Facilities (Chair)

Peter Thompson, Director of Strategy & Information

Danielle Hamm, Policy Manager

Committee Administrator:

Joanne McAlpine

Declarations of Interest: members of the Panel declared that it had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

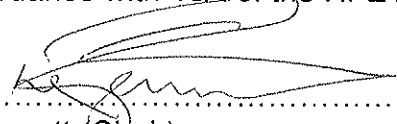
- papers for Licence Committee (44 pages)
- no tabled papers for this item

- The Panel also had before it:
- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers before it which included an executive summary, an application for the variation of premises, an appendix to the application form, email from the PR with the application form, floor plan of ground floor of WHRI, floor plan of laboratory G29, Renewal inspection report July 2009, and previous licence committee minutes.
2. The Panel noted that the research project R0161 is currently located on the fifth floor of the University Hospital Wales, and oocytes are donated to the project from IVF Wales located on the first floor of the same hospital building.
3. The Panel noted that research project R0161 has been licensed at centre 0049 since its inception, even though the research centre and IVF Wales are separate entities within this hospital.
4. The Panel noted that the PR of the centre has now applied to vary the centre's licence to move to new licensed premises.
5. The Panel noted that the inspectorate had reviewed the information that has been put before the Panel, and have stated that it meets the requirements as defined in Direction 0008.
6. The Panel noted that an inspection of the proposed new research premises was conducted on 14 April 2010.
7. The Panel noted that the new premises comprise of a single open-plan laboratory (G29), which has been produced by amalgamation of rooms 25, 26B, 26C and 26D on the WHRI ground floor.
8. The Panel noted that security at the premises was considered by the inspectorate to be appropriate and compliant with Code of Practice requirements.
9. The Panel noted that the centre aims to move all equipment from the existing premises to the new premises over the week of 3 May 2010, and will revalidate it once it is installed.
10. The Panel noted that the PR aims to start work on mouse oocytes on or around the 17 May 2010, and work on human oocytes under the project R0161 will re-start if and when the varied licence is issued by the HFEA.
11. The Panel noted that the PR is in the process of reviewing all processes and risk assessments for changes required due to the new work place.
12. The Panel noted that it was in receipt of updated staff details for the licence, the appropriate application form and all other relevant documentation on which to make a decision.
13. The Panel noted that the PR has reviewed all information provided to patients to correct any inaccuracies related to the change in licensed research premises.
14. The Panel noted that the PR has stated that all other activities within project R0161 would not change from those reviewed at the renewal inspection in July 2009 and that only the premises were changing.

The Panel's Decision

15. The Panel agreed to vary the centre's licence premises to Wales Heart Research Institute, School of Medicine, Cardiff University, Heath Park, Cardiff, CF14 4XN and agreed to assign a new centre number in accordance with 18A of the HFE Act 1990 (as amended).

Signed..........Date.....11/5/10.....
Mark Bennett (Chair)

