HFEA Executive Licensing Panel Meeting

21 April 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 8

Birmingham Women's Hospital, (0119), Application to vary to include embryo testing as a licensed activity allowing the provision of pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD) as licensed treatments.

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Juliet Tizzard, Acting Director of Strategy & Information	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Committee:

- papers for Licence Committee (26 pages)
- no tabled papers for this item

The Committee 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 which included an executive summary, an application to vary to include new licensable activities, an email from the Person Responsible and previous Licence Committee minutes.

2. The Panel noted the Person Responsible for centre 0119 applied on 6 April 2010 for a variation to the centre's licence to include embryo testing as a licensed activity.

3. The Panel noted that the centre has engaged Reprogenetics UK, Institute of Reproductive Sciences, Oxford Business Park, Oxford, as a third party to provide a genetics testing service. The genetics testing services will include comparative genomic hybridization (CGH) for aneuploidy screening (i.e. PGS), fluorescence in situ hybridisation (FISH) for detection of chromosomal translocations, and genetic marker and mutational analysis for single gene disorders (i.e. PGD).

4. The Panel noted that the Reprogenetics UK laboratory was established in 2008 and last year moved into the same building as HFEA centre 0035. Working with Reprogenetics UK, centre 0035 was granted a licence variation for PGS in November 2008 and for PGD in October 2009. Reprogenetics UK has applied for CPA accreditation and is awaiting inspection. An action plan for the application process has been previously provided to the HFEA Executive. Reprogenetics UK already provide PGS and PGD services to other HFEA licensed centres.

5. The Panel noted that a third party agreement has already been established between Birmingham Women's Hospital and Reprogenetics UK.

6. The PR at centre 0119 has supplied patient information and protocols prepared or modified in response to the proposed change in licensed treatments. The PR also supplied an appropriately completed application form of the correct type at the time of submission. These actions have fulfilled the requirements for such applications defined in Direction 0008, paragraph 17.

7. The Panel noted that in the executive summary the inspectorate states that discussion with the Scientific Director at the centre indicates that validation data for the embryo biopsy equipment and the biopsy and transportation methods has been obtained using blastomeres biopsied as part of research licence R0186 at centre 0119. The methods used in genetic analysis have been validated by the testing centre. This validation was acceptable to a Licence Committee in November 2008 and an Executive Licensing Panel in October 2009, which approved the licence variations submitted by (centre 0035) for PGS and PGD, respectively.

8. The Panel noted that the patient information and consent forms relating to PGS and PGD have been reviewed by the inspectorate and were considered to contain all the relevant information that is required by the 8th edition of the Code of Practice.

9. The Panel noted that the Executive are in support of this application for the variation to add the additional licence activities.

10. The Panel noted that the centre estimates that it is likely to treat around 12 PGD cases per year in the first instance.

11. The Panel agreed that in the light of the likely numbers of treatments that the centre will be carrying out per year, there are adequate staff to carry out the procedures and any additional work.

The Panel's Decision

12. The Panel agreed to vary the centre's licence to include the following activities to the licence embryo testing, pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD) as licensed treatments in accordance with 18A of the HFE Act 1990 (as amended).

Signed.....Date.....5/5/10.
Peter Thompson (Chair)