# HFEA Executive Licensing Panel Meeting

**24 February 2010**

21 Bloomsbury Street London WC1B 3HF

## Minutes – item 3

**Centre for Reproductive and Genetic Health (CRGH) (0044), Application to vary present licence to include PGD for beta thalassaemia major (OMIM# 141900) with HLA typing for named patients**

| Members of the Panel: | |
|---|---|
| Peter Thompson, Director of Strategy & Information (Chair)<br>Mark Bennett, Director of Finance & Facilities<br>Trish Davies, Director of Compliance | Committee Administrator:<br>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 ( 11 pages)
- no papers were tabled 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 noted that this application is for a variation to include PGD for beta thalassaemia major with HLA typing for named patients.

2. The Panel considered the papers which consisted of a redacted application form and a letter from the clinician treating the sick child.

3. The Panel noted that the condition had been previously licensed by a Licence Committee for use in PGD.

4. The Panel noted that the centre had considerable experience in PGD and in the use of PGD for HLA Tissue Typing.

5. The Panel noted that the patient couple (patient Mrs FAA and Mr ARAD) had a two year old daughter with the condition who has to have blood transfusions every four weeks.

6 The Panel noted that the letter from the clinician, supporting this application, provided comprehensive detail on the medical history of the child.

7. The Panel noted from the application that there is a 25% chance (1 in 4) for an embryo to be affected by beta thalassaemia.

8. The Panel noted that beta thalassaemia major is a fully penetrant disease which onsets before 1 year of age. Treatment is by means of blood transfusions every three weeks requiring hospital stays throughout life, resulting in commensurate social and educational deprivation. The high number of blood transfusions results in iron overload and only 75% of children survive to the age of 35 years old. The only long-term cure is a stem cell transplant, where there is a disease free survival rate of 98%. In comparison, unrelated transplantation had a disease free survival rate of no better than 60-70% at present.

9. The Panel referred to section 16 d (i) of the PGD decision tree and applied the tests for the purposes of PGD with HLA for beta thalassaemia.

<u>The Panel's Decision</u>

10. The Panel were satisfied that they had enough information on which to make a decision and decided to approve this application to vary the licence to include PGD for beta thalassaemia major, with HLA typing for named patients Mrs FAA and Mr ARAD.

Signed.....Date.....5/3/10.
Peter Thompson (Chair)