HFEA Executive Licensing Panel Meeting

24 February 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

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) Mark Bennett, Director of Finance & Facilities Trish Davies, Director of Compliance	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 (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 was 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 this condition had previously been 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 had a six year old child suffering from beta thalassaemia, who had an unrelated cord blood transplant outside the UK at the age of 2.

6. The Panel noted that the child had to have blood transfusions every three weeks and was on significant medication in order to control the condition.

7. The Panel noted from the application that there is a 25% chance (1 in 4) that an embryo will 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 noted that the clinician's letter mentioned there has been extensive HLA typing of the family in the home country and that none were a suitable match.

10. 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>

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

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