HFEA Licence Committee Meeting

24 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0044 (Centre for Reproductive and Genetic Health (CRGH)) – PGD for Factor XIII deficiency OMIM# 613225

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional)	Terence Dourado Legal Adviser: Sarah Ellson

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:

- Executive Summary
- PGD Application Form
- Redacted Peer Review
- Genetic Alliance Opinion

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note for Licence Committee

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre is licensed for PGD and has considerable experience of carrying out PGD.

2. The Committee was satisfied that the Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, ie. 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

3. The Committee noted that Factor XIII deficiency OMIM #613225 is inherited in an autosomal recessive pattern. Therefore, if an embryo inherits a copy of the faulty gene from both parents it will develop the disease, i.e. there is a 1 in 4 chance of the embryo having the abnormality.

4. The Committee noted that there is a significant risk that a person with the condition will develop a serious medical condition because it is fully penetrant.

5. The Committee considered that the condition is serious because it is a rare congenital bleeding disorder. The fetus may be affected prior to birth with intracranial haemorrhage; intrauterine fetal death and miscarriage. After birth there may be excessive umbilical bleeding; and in addition to the risk of intracranial haemorrhage, spontaneous bleeding can occur anywhere in the body. There is a lifelong risk of haemorrhage and therefore normal physical activity is restricted. Any acute bleeding has to be treated with cryoprecipitate or plasma-derived Factor XIII concentrate and has to be continued throughout life. Nonetheless, any intracranial haemorrhage has the potential to have a major impact on brain function, even if appropriate treatment is quickly given.

6. On the basis of the information presented, the Committee was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness

or any other serious medical condition. Accordingly, it was appropriate to grant the application under 1ZA(1)(b) of Schedule 2 to the Act.

7. The Committee agreed that the licence should be varied to authorise the testing of embryos for Factor XIII deficiency OMIM #613225, and that no conditions should be put on the licence in relation to the variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed ..... Date 9/3/2011

David Archard (Chair)