HFEA Licence Committee Meeting

29 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0088 (London Fertility Centre) – Variation application to perform PGD for Ehlers-Danlos Type IV – OMIM# 130050

Members of the Committee:	Committee Secretary:
	Terence Dourado
Anna Carragher (lay) – Chair	
Mair Crouch (Professional)	Legal Adviser:
Sue Price (Professional)	Sarah Ellson, Field Fisher Waterhouse LLP

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
- Application form
- Patient information
- Consent form
- Redacted peer review
- Joint Genetic Alliance UK and EDS 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

Tabled document:

- Addendum to the Genetic Alliance UK and EDS opinion

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre has been licensed to perform PGD since May 2008 and has appropriately trained and experienced staff to deliver the service.

2. The Committee noted 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, i.e. '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 Ehlers-Danlos Type IV is an autosomal dominant disorder. Only one copy of the affected gene is sufficient to cause the disorder, i.e. there is a 50% chance of the embryo being affected in a family where one parent is affected and the other is unaffected

4. The Committee noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is close to 100% penetrant. However, the age of detection of the phenotype may vary.

5. The Committee considered that the condition is serious. The condition is likely to present in young adult life. The symptoms primarily involve arterial and bowel complications but may also include excessive bruising, characteristic facial features such as sunken eyes, and thin and translucent skin with highly visible subcutaneous features. Complications are unpredictable and the outcome varied. There are no available treatments for the condition but symptoms are monitored closely including periodic arterial screening. The average age of death for those affected by

the condition is 50 years. The Committee considered that type of the condition was a life-limiting condition with risks of mortality at any age if the person has complications.

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 Ehlers-Danlos Type IV – OMIM# 130050, 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...8.8.2010

Anna Carragher (Chair)