HFEA Licence Committee Meeting

31 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0044 (Centre for Reproductive and Genetic Health (CRGH)) –PGD for Fraser Syndrome OMIM# 219000

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Sally Cheshire (lay) Mair Crouch (lay)	Terence Dourado Legal Adviser: Tom Rider, Field Fisher

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 UK 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 has considerable experience of carrying out PGD and that generic patient information about its PGD programme and associated consent form had been received by the HFEA.

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 Fraser Syndrome OMIM #219000 is inherited in an autosomal recessive pattern. Only one copy of the affected gene is sufficient to cause the disorder, i.e. there is a 1 in 4 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 fully penetrant.

5. The Committee considered that the condition is serious because its main features tend to be cryptophthamos (“hidden eye”), syndactyly (webbing of the fingers) and abnormal genitalia. Other features include absence of the kidneys (which can make the disorder fatal), congenital heart disease and laryngeal stenosis (narrowing of the larynx). Mental retardation occurs in 80% of survivors. The Committee also noted that in about 80% of cases the kidneys either fail to develop or develop abnormally, which could lead to still birth. Renal or pulmonary complications are also the reason of death in the first year in about 45% of new-borns with the condition. The treatment of the condition would involve major surgery to correct the malformations.

6. The Committee noted that although the condition’s symptoms are variable the only individuals who survive with the condition will be severely disabled.

7. The Committee reminded centres that given the rarity of the condition and its visual identifiers centres should be mindful of preserving the confidentiality of its patients.

8. 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 paragraph 1ZA(1)(b) of Schedule 2 to the Act.

9. The Committee agreed that the licence should be varied to authorise the testing of embryos for Fraser Syndrome OMIM #219000, 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…D M D… Date…14.4.2011

David Archard (Chair)