HFEA Licence Committee Meeting

30 April 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 6

Centre 0070 (The Bridge Centre) – Variation application to perform PGD for Muscle-Eye-Brain Disease, OMIM# 253280

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) – Chair Debbie Barber (Professional) Mair Crouch (lay)	Terence Dourado Legal Advisers: Mary Timms

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
- Two redacted peer reviews
- Genetic Interest Group (GIG) 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

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre already has considerable experience of carrying out PGD and had developed a large PGD programme.

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, 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 Muscle-Eye-Brain Disease, OMIM# 253280 is inherited in an autosomal recessive pattern. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, ie. there is a 25% chance of the embryo having the abnormality.

4. The Committee noted that there is a significant risk that those born with the affected gene will develop an abnormality because it is 100% penetrant.

5. The Committee noted that the condition is serious because it usually presents itself in very early childhood and patients severely affected tend not to live longer than two years. Those who survive infancy still die prematurely. Central nervous system abnormalities are always present, including moderate to severe mental retardation. Eye abnormalities including severe myopia, glaucoma, cataracts and retinal detachment are common. Furthermore, the Committee noted that the peer reviewer also identified frequent epileptic seizures in patients. The Committee noted that there is no cure for this condition.

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 Muscle-Eye-Brain Disease, OMIM# 253280 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....10.5.2010

Anna Carragher (Chair)