HFEA Licence Committee Meeting

31 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD for Micro Syndrome (WARBM) OMIM# 600118

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) Sue Price (professional)	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

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 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 Micro Syndrome (WARBM) OMIM #600118 is inherited in an autosomal recessive manner. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, iethere 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 abnormality will develop a serious medical condition because it is fully penetrant; with some variation in the degree of learning disability, severity of the seizure and visual impairment.

5. The Committee considered that the condition is serious because the particular mutation is associated with an early onset in affected individuals; It is a serious congenital and life-limiting condition which presents in the first year of life. Individuals with the condition develop progressive microcephaly (an abnormally small head and underdeveloped brain) associated with severe retardation of growth and development. The condition may be suspected before the onset of symptoms because of the features related to the eyes which include abnormally small cornea and congenital cataract. Patients have severe visual impairment due to a combination of the ocular abnormalities and cortical disfunction. A high proportion of patients suffer from seizures which may be difficult to control with anticonvulsant drugs. Motor development is usually severely impaired so that some children never learn to walk unaided and many children never develop speech. There is no treatment for the condition other than supportive. Children with the condition will remain dependent on carers for basic activities of daily living throughout their life; and life expectancy is reduced.

6. The Committee noted that given the rarity of the condition centres should ensure that any publication details do not lead to patient identification.

7. 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.

8. The Committee agreed that the licence should be varied to authorise the testing of embryos for Micro Syndrome (WARBM) OMIM #600118 and tha 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...14.4.2011

David Archard (Chair)