HFEA Licence Committee Meeting

28 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0044 (Centre for Reproductive and Genetic Health (CRGH)) – Application to vary present licence to include PGD for Gangliosidosis (GM1) OMIM# 230500

Members of the Committee: David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) Sue Price (professional)	Committee Secretary: Terence Dourado Legal Advisers: Graham Miles, Morgan Cole

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
- Signed application form (including any appendices)
- Redacted peer review
- Additional communication from centre 0044 confirming that both disease-associated mutations have been identified in the affected family.

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 has considerable experience of carrying out PGD and conducted 46 PGD cycles between 1st January 2008 and 31st December 2009. Furthermore, the Centre was CPA accredited in accordance with standards for the medical laboratory incorporating ISO 15189:2007 in December 2009.

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 Gangliosidosis (GM1) OMIM #230500 is inherited in an autosomal recessive pattern. An altered copy of the gene is inherited from both parents and there is therefore a 25% risk in any pregnancy.

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

5. The Committee considered that the condition is serious because it results in a steadily progressive neurodegeneration with systemic involvement which starts within the first six months of life and leads to death in early childhood. The condition would have a profound impact on the affected child and the whole family. There is no established effective treatment, although experimental approaches are being developed in animal models.

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 Gangliosidosis (GM1) OMIM #230500, 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 9:11:2010

David Archard (Chair)