HFEA Licence Committee Meeting

25 March 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 8

Centre 0044 (Centre for Reproductive and Genetic Health) – Variation application to perform PGD for Cerebral Cavernous Malformations (CCM), OMIM# 116860

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Rebekah Dundas (lay) Sue Price (Professional)	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 original application form
- Corrected application form
- Appendix 1
- Redacted peer review
- Supplementary comments from peer reviewer concerning the corrected application form

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 conducted 46 PGD cycles between 1 January 2008 and 31 December 2009.

2. The Committee noted that it had been presented with two application; a corrected version of an earlier application. The Committee made its decision in respect of the corrected application form.

3. 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'.

4. The Committee noted that Cerebral Cavernous Malformations (CCM) is inherited in an autosomal dominant inheritance pattern. Therefore only one copy of the affected gene is needed to cause the disorder. In this type of inheritance there is a 50% chance of the embryo inheriting the affected gene.

5. The Committee noted that there is a significant risk that those born with the affected gene will develop an abnormality because the condition is variable and penetrance can be in the range of 50 – 75%.

6. The Committee noted that the condition is serious because it is a relatively rare form of the condition that may involve any part of the central nervous system. In some cases it can be clinically silent while in others it can cause seizures, haemorrhages or focal neurologic deficit. The most common noticeable symptoms include seizures, recurrent headache, and cerebral haemorrhage. Age of onset is variable, sometimes occurring in infants and children. The condition can result in muscle weakness, paralysis, loss of sensation, hearing or vision loss and can be fatal if major cerebral haemorrhage occurs. Treatment includes anti-epileptic drugs and surgery; in some cases it can be curative but otherwise treatment is therapeutic only. The condition can be fatal if it causes severe brain haemorrhages

and living with the knowledge of this can severely affect a patient's quality of life.

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 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 Cerebral Cavernous Malformations (CCM) OMIM#116860 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.31/03/2010

David Archard (Chair)