HFEA Licence Committee Meeting

24 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0102 (Guy's Hospital) Macular Dystrophy Retinal 2 OMIM# 608051

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional)	Terence Dourado Legal Adviser: Sarah Ellson, 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 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 was licensed to provide PGD and has considerable experience of carrying out PGD.

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 Macular Dystrophy Retinal 2 OMIM #608051 is inherited in an autosomal dominant pattern. Therefore, only one copy of the affected gene is required to cause the disorder. In this type of inheritance there is a 1 in 2 chance of the embryo inheriting the affected gene.

4. The Committee noted that there is a significant risk that a person wi~~t~~h the condition will develop a serious medical condition because it is fully penetrant.

5. The Committee considered that the condition is serious because it affects an individual’s vision resulting in a central blind spot, impairing the vision from the part of the retina responsible for the sharpest vision and best colour perception. The age of onset of the condition for those at risk varies from 5-20 years of age and the severity of the symptoms can vary widely – there is no test to determine the level of expression that may present on an individual basis. The Committee noted that there is currently no gene-therapy available and it is not yet treatable.

6. The Committee recognised that the condition seriously impacts upon an individual’s quality of life; it noted the Genetic Alliance Opinion which states that sight is an important component of an individual’s ability to have an active and independent life, a patient with the condition will have reduced opportunity in their childhood (if onset is early), education and working life, and they must expect a life of gradually increasing visual impairment.

7. The Committee had regard to its PGD Explanatory Note and noted that where a condition has variable symptoms, the Licence Committee will base its determination of how serious the disability, illness or condition is, on the worst possible symptoms.

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 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 Macular Dystrophy Retinal 2 OMIM #608051, 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. 9/3/2011.

David Archard (Chair)