HFEA Licence Committee Meeting

25 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0102 (Guys Hospital) – PGD for Alpha-mannosidosis OMIM #248500

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Sally Cheshire (lay) Mair Crouch (lay) Jane Dibblin (lay) Rebekah Dundas (lay) Sue Price (professional)	Terence Dourado Legal Adviser: 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
- 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

1. The Committee had regard to its Decision Tree and was satisfied that the Centre has an established PGD programme 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 Alpha-mannosidosis OMIM #248500 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 a person with the abnormality will develop a serious medical condition because it is fully penetrant.

5. The Committee was satisfied that the condition is serious and noted that it has a wide range of clinical phenotypes from the mild to very severe. The condition has been classified into two major forms: The most severe form is less common and, in the first year of life, it presents with coarse facial features, enlargement of the liver and spleen, and rapidly progressive neurological damage; individuals with this form of the condition do not survive childhood; those with the milder form are likely to survive into adulthood but will suffer from learning difficulties, poor coordination and ataxia (inability to coordinate voluntary muscle movements). Other symptoms of the condition include coarse facial features and an abnormal skeletal development. Hearing problems, due to conductive and sensorineural (nerve) deafness, are common, and approximately half of those with the condition may have some visual impairment. The condition presents an immune-deficiency that predisposes an affected individual to infection. A destructive arthropathy (disease of a joint) may occur and this alongside ataxia may lead to some individuals to be users of wheel chairs. Adults with the condition would not be expected to be able to live independently.

6. The Committee based its consideration on the most serious form of a condition. Furthermore, it noted that although Alpha-mannosidosis has a variable phenotype and can be graded, the phenotype cannot be predicted in the instance.

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 Alpha-mannosidosis - OMIM #248500, 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...8/12/2010

David Archard (Chair)