HFEA Licence Committee Meeting

25 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0102 (Guys Hospital) – PGD for Autosomal Recessive Severe Combined Immunodeficiency with Bilateral Sensorineural Deafness OMIM# 267500

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 Autosomal Recessive Severe Combined Immunodeficiency with Bilateral Sensorineural Deafness 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 because patients with the condition will have a severely compromised immune system presenting in early infancy with recurrent infections, there is also additionally profound deafness. It noted that bone marrow transplants may offer a chance of treatment, however, the condition would need to be diagnosed and a compatible donor found before any major infection occurs. The Committee considered that even if a compatible donor was found, not all transplants are possible or successful for the condition.

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 Severe Combined Immunodeficiency with Bilateral Sensorineural Deafness - OMIM# 267500, 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)