HFEA Licence Committee Meeting

29 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0102 (Guys Hospital) – Variation application to perform PGD for Tyrosinaemia Type 1 - OMIM #276700

Members of the Committee:	Committee Secretary:
	Terence Dourado
Anna Carragher (lay) – Chair	
Mair Crouch (lay)	Legal Adviser:
Sue Price (Professional)	Sarah Ellson, Field Fisher Waterhouse LLP

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
- Generic PGD patient information
- A response from Genetic Alliance UK about the Tyrosinaemia PGD application

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 is already established and licensed for PGD.

2. 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, i.e. '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 Tyrosinaemia Type 1 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, i.e. 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 considered that the condition is serious because the condition presents in the first year of life. The symptoms, which may vary within a family, include severe liver dysfunction and renal involvement, growth failure and rickets. This can progress to liver failure with ascites, jaundice and gastro-intestinal bleeding, which if untreated would lead to death. Other symptoms include neurological crises with possible change in mental status; abdominal pain, peripheral neuropathy and respiratory failure. The Committee noted that treatment could be invasive and would certainly be unpleasant and without treatment a person with the condition would die before ten years of age.

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 Tyrosinaemia Type 1 - OMIM #276700, 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.....Anna Carragher.....Date....8.8.2010

Anna Carragher (Chair)