HFEA Licence Committee Meeting

29 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0102 (Guys Hospital) – Variation application to perform PGD for Czech dysplasia, metatarsal type also known as Progressive pseudorheumatoid dysplasia with hypoplastic toes
OMIM %609162

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
- Generic PGD patient information
- Redacted Peer Review
- Opinion on PGD application from Genetic Alliance UK
- The Centre's response to the Genetics Alliance UK 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 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 the condition is inherited in an autosomal dominant pattern. Therefore one copy of the affected gene is sufficient to cause the disorder, i.e. there is a 50% chance of the embryo being affected in a family where one parent is affected and the other is unaffected

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 but with variable expressivity.

5. The Committee considered that the condition is serious because the symptoms include severe joint pain and osteoarthritis from childhood affecting the spine, hips and knees with restricted mobility and flexion contractures; joint replacement surgery may be required as early as 12 years of age; shortening of the trunk secondary to severe curvature of the spine and abnormalities of the feet and toes secondary to short metatarsal bones. Treatment for the condition may include invasive surgery. Quality of life is significantly reduced although the impact on life expectancy or adult life span of a person with the condition was not apparent from the information available. It was recognised that there would be very limited experience of this rare 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 Czech dysplasia, metatarsal type also known as Progressive pseudorheumatoid dysplasia with hypoplastic toes - OMIM %609162, 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)