HFEA Licence Committee Meeting

16 December 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0070 (The Bridge Centre) – PGD for Hyper-IgE Recurrent Infection Syndrome, Autosomal Dominant OMIM #147060

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Mair Crouch (lay) Rebekah Dundas (lay) (via videoconference)	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 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 has a large 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 Hyper-IgE Recurrent Infection Syndrome, Autosomal Dominant OMIM #147060 is an autosomal dominant disorder. Only one copy of the affected gene is sufficient to cause the disorder, ie. there is a 50% chance of the embryo having the abnormality 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.

5. The Committee was satisfied that the condition is serious and noted that the condition is a primary immune deficiency characterised by recurrent skin boils, cyst-forming pneumonias, and extreme elevations of serum IgE. It is now recognised that other common manifestations include eczema, skin infections, several connective tissue and skeletal abnormalities. A rash in the newborn period subsequently evolves into an eczematoid dermatitis. Recurrent staphylococcal skin boils and bacterial pneumonias usually manifest in the first years of life. Skin infections are common. A characteristic facial appearance typically develops in adolescence. Skeletal abnormalities include low bone density resulting in trauma fractures, and scoliosis. Vascular abnormalities including middle-sized arterial tortuosity and aneurysms may occur. Individuals with the conditions typically survive into adulthood, but life span is often shortened. Most deaths are associated with Gram-negative (Pseudomonas) or fungal pneumonias. Lymphomas occur at an increased frequency. There is no cure for the condition. In many cases the quality of life is adversely affected, proportionate to the degree to which the sufferer is debilitated by recurrent infections and secondary complications, and the need for aggressive treatment. There is no effect on mental capacity but physical

activity and capacity is affected, which is complicated by damage to the lungs through abscesses and cysts.

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 Hyper-IgE Recurrent Infection Syndrome, Autosomal Dominant - OMIM #147060, 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 D.A.A. .... Date 31/12/2010

David Archard (Chair)