HFEA Licence Committee Meeting

14 June 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 5

Centre 0070 (The Bridge) – PGD for Severe Combined Immunodeficiency – autosomal recessive (OMIM #600802)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Mair Crouch (lay) Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Juliet Oliver, Field Fisher Waterhouse

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

- Cover sheet
- 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
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

Discussion

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied that the Centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

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, 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 Severe Combined Immunodeficiency – ~~autosomal recessive~~ (OMIM #600802) is a disorder that is inherited in an autosomal recessive manner. There is a 1 in 4 chance of an embryo being affected by this condition where both parents are carriers.

4. The Committee noted that this form of Severe Combined Immunodeficiency is associated with loss of JAK3.SCID is the result of an immune system so highly compromised that it is considered almost absent. The effects are typically present at birth and if untreated, affected babies usually die before their first birthdays. Symptoms include diarrhoea, ear infections and pneumonia, as well as severe mouth infections in affected children.

5. The Committee noted bone marrow transplantation carried out within the first 3 months of life can be an effective treatment, although there are special challenges to the immune system if a fully-matched donor is unavailable and it is not always effective for this particular SCID.

6. The Committee noted that the condition is serious because it is one of a severely impaired, often functionally absent, immune system. It usually presents soon after birth with failure to thrive, diarrhoea and recurrent infections. Treatment is possible with bone marrow transplantation but this is far from risk free and has associated long term complications. Roberts et al (2004) concluded that bone marrow transplantation is an effective

means for reconstitution of T-cell immunity in this disorder, but is less successful for restoration of B-cell and NK-cell functions. Affected individuals may be isolated in order to protect them from succumbing to infections from the normal environment. In most children the condition is fully penetrant and severe. Without treatment most children die by one year of age.

7. The Committee noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK.

8. 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 paragraph 1ZA(1)(b) of Schedule 2 to the Act.

9. The Committee noted that while they may grant approval, the centre providing PGD for the condition must also ensure that each individual case treated fulfills the severity criteria of Schedule 2 paragraph 1ZA of the HFE Act 1990 (as amended).

10. The Committee agreed to authorise the testing of embryos for Severe Combined Immunodeficiency – autosomal recessive (OMIM #600802). The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 27/06/2012

David Archard (Chair)