HFEA Licence Committee Meeting

7 March 2013

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

Minutes – Item 3

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD for Familial Dysautonomia (neuropathy, hereditary, sensory and automatic) Type 3 OMIM #223900

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Lauren Crawford
Rebekah Dundas (lay)	
Debbie Barber (professional)	Legal Adviser:
Jane Dibblin (lay)	Juliet Oliver, Field Fisher
Andy Greenfield (lay)	Waterhouse
Bishop Lee Rayfield	

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
- Additional Information from centre 0044 concerning treatment of the condition

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 supporting documents with this application did not contain either a Peer Review or Genetic Alliance Opinion. The Committee were satisfied that they had, in any event, sufficient information before them on which to make a decision.

3. 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'.

4. The Committee noted that Familial Dysautonomia, OMIM #223900 is inherited in an autosomal recessive manner. There is therefore a 1 in 4 chance of the embryo being affected by this condition if both parents are carriers..

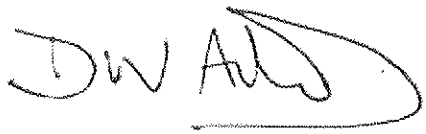
5. The Committee noted that affected children show abnormal development of the nervous system associated with demyelination in various regions. This leads to a variable clinical presentation from progressive loss of nerve cells in the autonomic and sensory nervous systems. It includes vomiting crises, unsteady gait, and decreased perception of pain. The depletion of nerve cells in the autonomic system causes problems with unstable heart rate, blood pressure, and body temperature control, as well as gastrointestinal dysfunction, poor motor co-ordination, and emotional instability. Abnormal development of the sensory nervous system results in poor perception of pain, heat and cold. This means that affected individuals can injure themselves without being aware of it.

6. The Committee considered that the condition is serious because this deterioration of the nervous system worsens throughout life and causes multiple health problems that lead to the death of 50% of the deaths of those

affected by adulthood. Presentation is in childhood, typically around puberty, the effects of the genetic mutation are fully penetrant and distressing..

7. The Committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it 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. The Committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

8. The Committee agreed to authorise the testing of embryos for Familial Dysautonomia (Type 3), OMIN #223900. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed:  Date: 26/03/2013

David Archard (Chair)