HFEA Licence Committee Meeting

25 August 2011

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

Minutes – Item 4

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD for Glycogen Storage Disease Type 1A (OMIM #232200)

Members of the Committee: Anna Carragher (lay) - Chair Debbie Barber (professional) Sally Cheshire (lay) Mair Crouch (lay) (videoconference) Rebekah Dundas (lay) (via videoconference) Sue Price (professional)	Committee Secretary: Terence Dourado Legal Adviser: Rosalind Foster, Beachcroft

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
- Opinion from Genetic Alliance UK
- Abstract of paper referred to in 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)
- 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

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre has considerable experience of carrying out PGD and that generic patient information about its PGD programme and associated consent form had been received by the HFEA.

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 Glycogen Storage Disease Type 1A (OMIM #232200) is inherited in an autosomal recessive manner. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, ie there is a 1 in 4 chance of the embryo having the abnormality.

4. The Committee was satisfied 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, which presents between birth and four months, is serious because it causes an accumulation of glycogen and fat in the liver and kidneys. Symptoms can include seizures, growth retardation, osteoporosis (brittle and fragile bones), gout, renal disease, high blood pressure, pancreatitis, hepatic tumours and changes in brain function. Furthermore, the Committee noted that although affected individuals live into adulthood, the brain deteriorates; changes in IQ, MRI findings and EEG may correlate with the frequency of hypoglycaemic episodes. An affected individual is at risk of liver cancer and may require liver or renal transplants. Treatment support is palliative only and may only slow progression without clear improvement. The Committee also noted the comments of the peer reviewer and that the peer reviewer considered that the condition was appropriate for PGD.

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 paragraph 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 Glycogen Storage Disease Type 1A (OMIM #232200) 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 Date 14/09/2011

Anna Carragher (Chair)