HFEA Statutory Approvals Committee

27 February 2014

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

Minutes – Item 7

Centre 0006 (The Lister Fertility Clinic) – PGD application for Congenital Disorder of Glycosylation type 1a OMIM #212065

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Mary Porteous	Committee Secretary: Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: Hossam Abdalla left the meeting before this item as he is the PR (Person Responsible) at this centre. The Members present declared no conflicts in relation to this item.

The following papers were considered by the Committee

- Executive summary
- Application form
- Redacted peer review

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) (“the Act”)
- 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 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 Congenital Disorder of Glycosylation type 1a (OMIM #212065) is inherited in an autosomal recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers.

4. The Committee noted that Congenital Disorder of Glycosylation type 1a is a multi-system disorder. Affected individuals have severe and significant cognitive impairment, severely delayed language and motor development, inability to walk, seizures, impaired growth, difficulties feeding and skeletal deformities. 20% of affected children do not survive the first year of life due to severe infections, liver insufficiency or cardiomyopathy.

5. The Committee noted that onset is typically within the first month of birth and that the condition is fully penetrant.

6. The Committee noted that if a child had this condition in its most severe form, it would not survive the neonatal period.

7. The Committee noted that there is no curative treatment for this disorder.

8. The Committee noted that the application is supported by the Peer Reviewer.

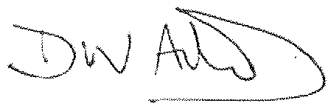
9. The Committee welcomed the advice of its Advisor, Mary Porteous, who confirmed that the condition was as described in the papers and that the condition is highly variable but relatively predictable within families. The adult onset form can still be severe and that is a multi-system disorder.

10. The Committee considered that the condition is serious because this is a severe, untreatable multisystem disorder and with an almost universal poor prognosis it almost always leads to severe neurological problems, multisystem failure and death in the neonatal period or infancy in those with the severe form of the condition.

11. 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) and (2) of Schedule 2 to the Act.

12. The Committee agreed to authorise the testing of embryos for Congenital Disorder of Glycosylation type 1a (OMIM #212065).

Signed: Date: 11/03/2014



David Archard (Chair)