HFEA Statutory Approvals Committee

20 November 2014

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

Minutes – Item 6

Centre 0035 (Oxford Fertility Clinic) – PGD application for X-linked Opitz G / BBB Syndrome OMIM #300000

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Rebekah Dundas (lay) Jane Dibblin (lay) Advisor: Dr Anne Lampe	Trent Fisher Legal Adviser: Ros Foster, Browne Jacobson Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: The Members declared no conflicts in relation to this item

The following papers were considered by the Committee:

- Application form
- Executive Summary
- Redacted peer reviews
- 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) ("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 X-linked Opitz G / BBB Syndrome OMIM (#300000) is inherited in an X-linked pattern and there is a 1 in 4 chance of an embryo being affected with the condition. The Committee noted that the application was for the X-linked condition which is caused by a mutation in the MID1 gene on the X chromosome. It further noted that this was not an application for sex testing.

4. The Committee noted that less than half of individuals affected by the condition suffer from intellectual disabilities and in more severe cases breathing and swallowing problems, heart defects and facial abnormalities may be present. Complications with the trachea can lead to choking when eating. The X-linked condition tends to include the cleft lip, with or without the cleft palate and abnormality of the urethra and penis (hypospadias) in a majority of affected males.

5. The Committee noted that the condition is present from birth.

6. The Committee noted that currently there is no cure for the condition however treatment for the symptoms may include a variety of surgical options as well as a tracheostomy which may be required to correct swallowing and breathing problems.

7. The Committee noted that the application is consistent with the Peer Review.

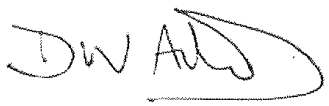
8. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition was as described in the papers. The Committee accepted her advice.

9. The Committee considered that the condition is serious because severely affected children will require a wide range of surgical and neuropsychological treatments from a young age and continued monitoring for the rest of their lives.

10. 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.

11. The Committee agreed to authorise the testing of embryos for X-linked Opitz G / BBB Syndrome (OMIM #300000) caused by the MID1 gene on the X chromosome.

Signed: Date: 3 December 2014



David Archard (Chair)