HFEA Statutory Approvals Committee

24 April 2014

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

Minutes – Item 4

Centre 0102 (Guy's Hospital) – PGD application for X-Linked Periventricular Heterotopia OMIM#300049

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Rebekah Dundas (lay) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Peter Turnpenny	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole 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

- 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 X Linked Periventricular Heterotopia (PNH) (OMIM #300049) is inherited in an X-linked dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition if the mother is affected. Affected males will not survive and affected females will always be symptomatic.

4. The Committee noted that X Linked PNH is an X linked condition in which the nerve cells do not migrate properly to the brain cortex during the fetal development in the first and second trimester of pregnancy resulting in a 'clumping' around the ventricles. This condition is usually fatal in male pregnancies and they tend to miscarry in the first trimester. The effect in females is variable, but those who show signs of the condition will have seizures or epilepsy with the onset usually in the teenage years. Individuals also have an increased risk of strokes due to abnormal blood clotting and may also present with other cardiovascular abnormalities.

5. The Committee noted that there is no curative treatment for X linked Periventricular Heterotopia. Treatment is symptomatic with medication to treat the epilepsy/seizures and to control blood pressure. Regular monitoring of the condition is required and patients may need ultrasound scans and echocardiograms to monitor the effects of this condition.

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

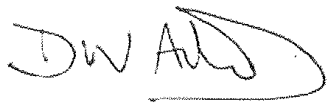
7. The Committee welcomed the advice of its Advisor, Peter Turnpenny, who confirmed that the condition was as described in the papers and further explained that most females with the gene mutation would be affected in some cases extremely mildly.

8. The Committee considered that the condition is serious because male embryos will die in utero and affected females will suffer seizures with an increased risk of stroke with further cardiovascular abnormalities.

9. 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.

10. The Committee agreed to authorise the testing of embryos for X Linked Periventricular Heterotopia (OMIM #300049)

Signed: Date: 07/05/2014



David Archard (Chair)