HFEA Statutory Approvals Committee

20 November 2014

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

Minutes – Item 5

Centre 0044 (Centre for Reproductive and Genetic Health) – PGD application for Leukoencephalopathy with Vanishing White Matter OMIM #603896

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Anne Lampe	Committee Secretary: 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:

- Executive summary
- Application form
- Redacted peer review
- Genetic Alliance opinion
- One redacted public comment

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 Leukoencephalopathy with Vanishing White Matter (OMIM #603896) 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 affected individuals suffer a neurological disorder characterised by variable neurologic features, including progressive cerebellar ataxia (failure of muscular coordination), spasticity, and cognitive impairment associated with white matter lesions on brain imaging.

5. The Committee noted that other symptoms include optic atrophy (degeneration of vision), epilepsy, loss of motor functions, irritability, vomiting and coma. Rapid neurologic deterioration can occur following minor head trauma. This condition can be fatal in childhood onwards, and it causes neurological deterioration.

6. The Committee noted that the age of onset can range from early infancy to, more rarely, adulthood. Affected females may develop ovarian failure.

7. The Committee noted that currently there is no curative treatment for Leukoencephalopathy with Vanishing White Matter.

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

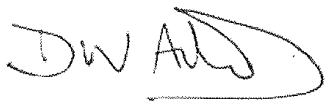
9. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition was as described in the papers and added that the condition causes relentless neurological deterioration. The Committee accepted her advice.

10. The Committee considered that the condition is serious because it is a severe neurological disorder with the possibility of death in children and that there is no current curative treatment.

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 Leukoencephalopathy with Vanishing White Matter (OMIM #603896)

Signed: Date: 3 December 2014



David Archard (Chair)