HFEA Statutory Approvals Committee

30 October 2014

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

Minutes – Item 3

Centre 0006 (The Lister Fertility Clinic) – PGD application for Familial Hemophagocytic Lymphohistiocytosis 5 OMIM #613101

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Debbie Barber (professional) Rebekah Dundas (lay) Jane Dibblin (lay) Advisor: Dr Peter Turnpenny	Committee Secretary: Lauren Crawford, Committee Officer Legal Adviser: Dawn Brathwaite, Mills & Reeve

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

The following papers were considered by the Committee:

- Executive summary
- PGD application form
- Redacted Peer Review form
- 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 Familial Hemophagocytic Lymphohistiocytosis 5 OMIM #613101 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 Familial Hemophagocytic Lymphohistiocytosis 5 involves over production and activation of normal infection fighting cells. This can lead to fever and damage to the liver and spleen. The condition can result in impaired muscle control, brain seizures, paralysis, blindness and coma. Individuals also have an increased risk of developing some types of cancers

5. The Committee noted that typically symptoms of Familial Hemophagocytic Lymphohistiocytosis 5 develop within the first year of birth.

6. The Committee noted that there is no curative treatment for Familial Hemophagocytic Lymphohistiocytosis 5. Symptoms may be managed with chemotherapy, immunotherapy and steroids. Bone marrow transplants may also be used to treat this condition. Management does not alleviate most symptoms and quality of life is severely impacted for individuals who have this condition. If untreated a 50% mortality rate is associated with this condition.

7. The Committee welcomed the advice of its advisor, Dr Peter Turnpenny. Dr Turnpenny confirmed that the condition was as is described in the papers. He also confirmed that treatment options are not easily accessible and in most cases are ineffective.

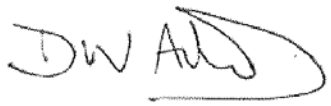
8. The Committee noted that the application is consistent with the Peer Review and is also supported by the Genetic Alliance.

9. The Committee considered that the condition is serious because it is a life threatening disease that affects the immune system from an early age and has a high mortality rate if untreated.

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 Familial Hemophagocytic Lymphohistiocytosis 5 OMIM #613101.

Signed: Date: 13/11/2014



David Archard (Chair)