HFEA Statutory Approvals Committee

25 September 2014

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

Minutes – Item 2

Centre 0119 (Birmingham Women's Hospital) – PGD application for Familial Dilated Cardiomyopathy caused by mutations in TROPONIN T2 gene (TNNT2), OMIM #191045

Members of the Committee: David Archard (lay) Chair Debbie Barber (professional) Rebekah Dundas (lay) Jane Dibblin (lay) Hossam Abdalla (professional) Advisor: Dr Edward Blair	Committee Secretary: Sam Hartley, Head of Governance and Licensing 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
- 3 comments from the public
- 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 Dilated Cardiomyopathy is inherited in an autosomal dominant manner which means there is a 50% chance of having an affected child in each pregnancy.

4. The Committee noted that initial symptoms of Familial Dilated Cardiomyopathy include shortness of breath, irregular heartbeat, extreme fatigue and fainting episodes. Often the first sign of the condition is sudden death, which can occur any time from infancy to late adulthood.

5. The Committee noted that there is no curative treatment for this condition; however, heart failure may be managed with medical therapy and implantable defibrillators. Cardiac transplantation may be required in some cases.

6. The Committee noted that the application is consistent with the Peer Review and is also supported by the Genetic Alliance. The Committee further welcomed the considered and valuable comments from the public on this condition.

7. The Committee welcomed the advice of its advisor, Dr Edward Blair, who confirmed that the condition was as described in the papers. He further

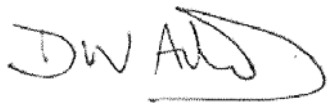
advised that the condition was bi-phasic – onset can occur in young children as well as older adults.

8. The Committee considered that the condition is serious due to the risk of sudden death and lack of curative treatment. The Committee further noted that the penetrance is variable but high.

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 Familial Dilated Cardiomyopathy caused by mutations in TROPONIN T2 gene (TNNT2), OMIM #191045.

Signed: Date: 07/10/2014



David Archard (Chair)