HFEA Statutory Approvals Committee

30 January 2014

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

Minutes – Item 2

Centre 0044 (The Centre for Reproductive and Genetic Health (CRGH)) – PGD application for Catecholaminergic Polymorphic Ventricular Tachycardia OMIM #604772

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

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 Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT1) (OMIM #604772) is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.

4. The Committee noted that CPVT1 is an arrhythmogenic disorder of the heart characterised by a reproducible form of polymorphic ventricular tachycardia induced by physical activity, stress, or catecholamine infusion, which can deteriorate into ventricular fibrillation (heartbeat irregularity). Patients present with recurring fainting, seizures or sudden death after physical activity or emotional stress. Clinical penetrance in this disease ranges from 25% to 100%, with an average of between 70% and 80%.

5. The Committee noted that symptoms are likely to develop in affected individuals aged under 10 years old, onset can occur in affected individuals aged up to 30 years old.

6. The Committee noted that the treatments for CPVT1 include medication and an automatic internal defibrillator is occasionally needed in patients with this condition. When untreated, mortality from CPVT1 is high, reaching 30% to 50% by the age of 30 years.

7. The Committee noted that the application is supported by the Genetic Alliance UK and the Peer Reviewer.

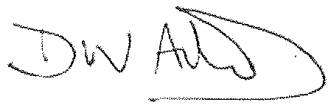
8. The Committee did not receive advice from an advisor at this meeting and agreed that the information in paperwork was sufficient for them to consider the item in their absence.

9. The Committee considered that the condition is serious because sudden death can occur and the quality of life for affected individuals can be limited physically and emotionally.

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) of Schedule 2 to the Act.

11. The Committee agreed to authorise the testing of embryos for Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT1) (OMIM #604772).

Signed: Date: 13/02/2014



David Archard (Chair)