HFEA Licence Committee Meeting

1 March 2012

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

Minutes – Item 1

Centre 0102 (Guys Hospital) – PGD for Catecholaminergic Polymorphic Ventricular Tachycardia 2 (OMIM #611938)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Mair Crouch (lay) (videoconference) Sue Price (professional) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Tom Rider, Field Fisher Waterhouse

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- PGD Application form: Ref 1447
- 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)
- 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 is experienced in 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 Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, ie. '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 Tachychardia 2 (CPVT2) (OMIM #611938) is an inherited arrhythmogenic disorder of the heart, characterised by cardiac electrical instability in individuals without structural cardiac abnormalities. It is the less common form of CPVT.

4. The Committee noted that it is inherited in an autosomal recessive manner. There is therefore a 1 in 4 chance of an embryo being affected by this condition if both parents are carriers.

5. The Committee noted that penetrance of this condition is variable between 25-100%, the average is 70-80%. The condition presents in early childhood with recurrent loss of consciousness, seizures or sudden death due to cardiac arrythmia.

6. The Committee noted that treatment is available for CPVT2 and that it requires either long term treatment with beta blockers or a surgical procedure with insertion of an implantable defibrillator (ICD). Left untreated the mortality rate is very high and even with treatment death may occur due to cardiac arrest. Having an ICD impacts on the quality of life and

individuals are required to avoid competitive sports and all strenuous exercise.

7. The Committee considered that the condition is serious because a child with this condition will have a very restricted life in comparison to their peers. Parents must live with the constant knowledge that their child is at risk of sudden death and with the burdens of continuing hospital and clinic visits.

8. The Committee noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK. The Genetic Alliance statement is endorsed by the British Heart Foundation.

9. The Committee had regard to its explanatory note and noted that on the basis of the information presented, given the conditions 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. Accordingly, it was appropriate to grant the application under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

Decision

10. The Committee agreed to authorise the testing of embryos for Catecholaminergic Polymorphic Ventricular Tachychardia 2 (CPVT2) (OMIM #611938). The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 13/03/2012

David Archard (Chair)