HFEA Statutory Approvals Committee

11 December 2014

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

Minutes – Item 1

Centre 0201 (Edinburgh Assisted Conception Unit) – PGD application for Familial Hypertrophic Cardiomyopathy type 1 OMIM #192600, type 3 OMIM #115196, type 7 OMIM #613690 and type 10 OMIM #608758

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Trent Fisher
Sue Price (professional)	
Debbie Barber (professional)	Legal Adviser:
	Graham Miles (Blake Morgan)
Advisor:	
Dr Edward Blair	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
- Email from Dr Thong confirming the types applied for

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 Hypertrophic Cardiomyopathy type 1 (OMIM #192600), type 3 (OMIM #115196), type 7 (OMIM #613690) and type 10 (OMIM #608758) are all 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 a carrier.

4. The Committee noted that a Familial Hypertrophic Cardiomyopathy type 1, 3, 7 and 10 causes an overgrowth of the muscle on the left ventricle. Individuals may initially have no symptoms but are prone to progressive heart failure and even sudden cardiac death that is particularly common in late teenage and early adult life. Sudden death is frequently the first manifestation of the disease, often occurring without any warning signs. Approximately 5 to 10 percent of individuals progress to end stage disease with heart failure.

5. The Committee noted that other common symptoms include shortness of breath, chest pain, palpitations, dizziness and blackouts. Affected individuals are at an increased risk of atrial fibrillation which can have significant morbidity due to increased risk of blood clots and symptomatic deterioration.

6. The Committee noted that the condition is widely variable between individuals, even within a family, and that symptoms most often become

apparent during adolescence or young adulthood although they may also develop in infancy, childhood or later in life.

7. The Committee noted that there are no curative treatments available for Familial Hypertrophic Cardiomyopathy types 1, 3, 7 and 10. Treatments for symptoms may include a cardiac transplant or the use of an implantable defibrillator, both of which carry risks of further complications.

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

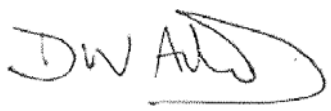
9. The Committee welcomed the advice of its Advisor, Dr Edward Blair, who confirmed that the condition was as described in the papers and added that there is a high rate of penetrance across Familial Hypertrophic Cardiomyopathy types 1, 3, 7 and 10.

10. The Committee considered that the condition is serious due to the high rate of penetrance, the risk of heart failure and death and treatment for symptoms of the condition also carry high risks of further complications.

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 Familial Hypertrophic Cardiomyopathy type 1 OMIM #192600, type 3 OMIM #115196, type 7 OMIM #613690 and type 10 OMIM #608758**.**

Signed: Date: 22/12/2014



David Archard (Chair)