# HFEA Statutory Approvals Committee

## 27 June 2013

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

### Minutes – Item 1

**Centre 0078 (IVF Hammersmith) – PGD application for Familial Hypertrophic Cardiomyopathy 4 (CMH4) OMIM #115197**

| Members of the Committee: | Committee Secretary: |
|---|---|
| David Archard (lay) Chair | Lauren Crawford |
| Sue Price (professional) | |
| Rebekah Dundas (lay) (Videoconference) | Legal Adviser: |
| Debbie Barber (lay) | Stephen Hocking, DAC Beachcroft |

Declarations of Interest:

Debbie Barber works at a licensed centre which collaborates with IVF Hammersmith, but she is not involved in any work with PGD.

The following papers were considered by the Committee

- Cover sheet
- Executive Summary
- PGD Application form
- Redacted Peer Review
- Genetic Alliance Opinion
- Patient Comment

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 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 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 Familial Hypertrophic Cardiomyopathy 4 (CMH4OMIM #115197) is inherited in an autosomal dominant pattern. There is therefore a 1 in 2 chance of the embryo being affected by this condition where a parent is affected.

4. The Committee noted the symptoms of CMH4 include dyspnoea (shortness of breath), chest pain, palpitations, light-headedness, fatigue, and fainting. There is a risk of sudden cardiac death. Symptoms can be readily provoked by exercise. Sudden cardiac death may be the first manifestation of the disease.

5. The Committee noted that there are no treatments that modify the underlying disease process. Individuals with CMH4 have an increased risk of sudden cardiac death and their lifestyle choices are restricted by the disease. The condition is progressive and affected individuals will need regular hospital appointments, medication and may require surgery.

6. The Committee noted the comments from the Peer Review which highlight the incomplete penetrance of this disorder but that, based on current literature, an estimate of >70% lifetime penetrance is suggested. There are insufficient studies to give a more reliable figure for lifetime penetrance.

7. The Committee considered that the condition is serious because CMH4 is a significant cause of sudden, unexpected cardiac death. Although sudden death occurs most often in young adults and adolescents it may occur at any age.

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

9. The Committee noted the patient comment received. It was very helpful and moving.

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 Familial Hypertrophic Cardiomyopathy 4 (CMH4 4, OMIM #115197). The Committee confirmed that this condition will be added to the published list of condition for which PGD may be carried out.

Signed: Date: 17/07/2013

David Archard (Chair)