HFEA Licence Committee Meeting

29 September 2011

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

Minutes – Item 2

Centre 0102 (Guy's Hospital) – PGD for Arrhythmogenic Right Ventricular Cardiomyopathy/ Dysplasia (ARVC/D), Autosomal Dominant

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Sally Cheshire (lay) (videoconference) Mair Crouch (lay) (videoconference) Rebekah Dundas (lay) (videoconference) Sue Price (professional)	Terence Dourado Legal Adviser: Graham Miles, Morgan Cole

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:

- Executive Summary
- PGD application form with additional information
- Redacted peer review form
- Redacted supporting email
- 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

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre has considerable 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 Arrhythmogenic Right Ventricular Cardiomyopathy/ Dysplasia (ARVC/D), Autosomal Dominant is a type of cardiomyopathy which is inherited in a dominant pattern. Only one copy of the affected gene is required to cause the disorder, i.e. there is a 1 in 2 chance of the embryo being affected in a family where one parent is affected and the other is unaffected.

4. The Committee noted that the degree of penetrance of the condition is not 100 % and is highly variable in that some affected individuals may not meet established clinical criteria. However, such individuals may still be at risk of cardiovascular events including arrhythmias. At its most serious, there is a risk of sudden cardiac death.

5. The Committee considered that the condition is serious because it is a progressive myocardial disorder characterised by fibrofatty replacement of the myocardium, predisposing to ventricular tachycardia and sudden death in those affected. It primarily affects the right ventricle and with time it may also involve the left ventricle. The Committee noted that the presentation of the disease is highly variable, even among family members who have the same pathogenic mutation. However, affected individuals may require a number of invasive treatments, as well as life-long monitoring of their condition. Treatments include various antiarrhythmic medications, implantable cardioverter-defibrillators (ICD) and heart transplantation.

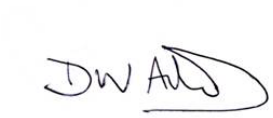
Nevertheless, the Committee noted that even with treatment, affected individuals have a threat of sudden death.

6. 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.

7. After a thorough discussion regarding the seriousness of the condition the Committee agreed that on the basis of the information presented, the Committee 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.

8. The Committee agreed to authorise the testing of embryos for Arrhythmogenic Right Ventricular Cardiomyopathy/ Dysplasia (ARVC/D), Autosomal Dominant. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 11/10/2011



David Archard (Chair)