HFEA Licence Committee Meeting

26 May 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0102 (Guy's Hospital) – PGD to perform Muscular Dystrophy-dystroglycanopathy Type A5 OMIM #613153

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Sally Cheshire (lay) Jane Dibblin (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional)	Terence Dourado Legal Adviser: Tom Rider, Field Fisher

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
- Application form
- Genetic Alliance opinion
- Redacted Peer Review

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.

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 Muscular Dystrophy-dystroglycanopathy Type A5 OMIM #613153 is inherited in an autosomal recessive manner. An affected embryo inherits a copy of the faulty gene from both parents, ie there is a 1 in 4 chance of the embryo having the abnormality.

4. The Committee noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is fully penetrant.

5. The Committee considered that the condition is serious because the age of onset is from birth to early infancy and it typically presents with muscle weakness during this stage, although the Committee noted that there is some variability in when affected individuals may be recognised as having the condition. Affected babies appear floppy with poor muscle tone and few movements, followed by a delay or inability to sit unsupported or walk. The condition tends to deteriorate as the muscles become progressively weaker. Complications such as rigidity of the joints of spine may develop over time resulting in spinal deformities and difficulties with breathing which can affect the quality of life and shorten the life span. Some children may have learning difficulties, structural brain or eye abnormalities and epilepsy. Those affected will require specialised support and independent living is unlikely.

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

7. 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 Muscular Dystrophy-dystroglycanopathy Type A5 OMIM #613153 and that no conditions should be put on the licence. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 09/06/2011

David Archard (Chair)