HFEA Licence Committee Meeting

28 July 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0102 (Guy's Hospital) – PGD for Bethlem Myopathy OMIM# 158810

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Anna Carragher (lay) Sue Price (professional)	Terence Dourado Legal Adviser: Sarah Ellson, 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
- PGD application form
- Redacted peer review
- Emails between peer reviewer and Executive
- Emails between applicant and Executive

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

Tabled document

- Genetic Alliance Opinion

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 Bethlem Myopathy OMIM# 158810 is inherited in an autosomal dominant manner. 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 considered 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 its symptoms include flexion contractures of the fingers, wrists, elbows and ankles, muscle weakness, follicular hyperkeratosis and keloid scarring. The Committee noted that although symptoms may be highly variable in and between families, affected individuals, even with milder cases, may develop respiratory complications which require ventilatory support at night. Furthermore, it noted that age of onset of the condition can be from prenatal to middle adult life and lifespan has been reported to be reduced due to respiratory failure caused by diaphragmatic weakness. There is no

cure for the condition, which for many affected individuals by aged 40 has serious implications for their mobility.

6. 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. Accordingly, it was appropriate to grant the application under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

7. The Committee agreed to authorise the testing of embryos for Bethlem Myopathy OMIM# 158810 and that no conditions should be put on the licence in relation to the variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 03/08/2011

David Archard (Chair)