HFEA Licence Committee Meeting

28 July 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0102 (Guy's Hospital) – PGD for Gaucher Disease Type III OMIM# 231000

Members of the Committee: David Archard (lay) – Chair Anna Carragher (lay) Sue Price (professional)	Committee Secretary: 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
- Opinion from Genetic Alliance UK
- Emails between applicant and Executive
- LC minutes – initial support for Gaucher disease type II – 24 Nov 2004
- LC minutes – application to vary licence to include PGD for Gaucher disease type II – 9 June 2005

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 Gaucher Disease Type III OMIM# 231000 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 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 frequent seizures, ataxia, problems with swallowing, enlarged liver and/or spleen and visual and auditory problems. The Committee noted that the severity of symptoms increases as the condition progresses, the age of onset is most common during infancy or childhood and lifespan is generally significantly shortened with death occurring as early as during teenage years.

6. The Committee noted that there are evolving enzyme replacement treatments that, in the future, may change the outcomes for affected individuals, however, at present these are not widely available nor fully evaluated.

7. The Committee noted paragraph 10.5 of the Code of Practice (8th edition)/ HFEA guidance for Centres: 'The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.'

8. 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.

9. The Committee agreed that the licence should be varied to authorise the testing of embryos for Gaucher Disease Type III OMIM# 231000 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)