HFEA Licence Committee Meeting

25 August 2011

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

Minutes – Item 2

Centre 0119 (Birmingham Women's Hospital) – PGD for Mucopolysaccharidosis III (MPS-III) Type B (OMIM #252920); MPS-III Type C (OMIM #252940); and MPS-III Type D (OMIM #252930)

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) - Chair Debbie Barber (professional) Sally Cheshire (lay) Mair Crouch (lay) (videoconference) Rebekah Dundas (lay) (via videoconference) Sue Price (professional)	Terence Dourado Legal Adviser: Rosalind Foster, Beachcroft

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
- Email from centre 0119 (3 August 2011)
- Letter from clinical geneticist working with centre 0119 (3 August 2011)
- Hrebicek M et al (2006) Mutations in TMEM76* Cause
- Mucopolysaccharidosis IIIC (Sanfilippo C Syndrome). The American Journal of Human Genetics 79: 807-819

Licence Committee papers and minutes – 30 June 2011

- Executive Summary
- PGD application form
- Annex to the PGD application form
- Redacted Peer Review
- Genetic Alliance opinion
- LC minutes – 30 June 2011

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)
- 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 Paper

- Executive Summary
- Supplementary information: Comment on variable expressivity and incomplete penetrance provided by Dr Dagan Wells, Reprogenetics UK, Oxford

1. The Committee noted that it first considered the application on 30 June 2011 but adjourned its determination to request information regarding penetrance in relation to the condition. The Committee noted that it had since received supplementary information regarding penetrance in order to aid its decision making.

2. 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 form had been received by the HFEA.

3. The Committee reminded itself that MPS III type A had been licensed for treatment using PGD.

4. The Committee was satisfied 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'.

5. The Committee noted that Mucopolysaccharidosis III (MPS-III) Type B (OMIM #252920); MPS-III Type C (OMIM #252940); and MPS-III Type D (OMIM #252930) are inherited in an autosomal recessive manner. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, ie there is a 1 in 4 chance of the embryo having the abnormality.

6. The Committee was satisfied that there is a significant risk that a person with any one of these metabolic diseases will develop a serious medical condition because the conditions are fully penetrant, albeit with variable expressivity.

7. The Committee considered that the conditions are serious because all four types give rise to a severe, life limiting and destructive illness. Severe behavioural disturbance usually starts in the first five years of life, with gradual regression of skills from 6 to 15 years. Many individuals with the condition die in their teens but a significant number survive with a continuing degenerative disease until their 20s – 30s.

8. The Committee noted that although treatments are evolving, these are still in the early experimental stages and at present there are no licensed treatments. The Committee also noted the comments of the peer reviewer and that the peer reviewer considered that the condition was appropriate for PGD. The peer reviewer considered these conditions to be probably the most destructive in terms of the ability of the family to cope with the illness.

9. On the basis of the information presented, the Committee was satisfied that there is a significant risk that a person with any one of the abnormalities 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.

10. The Committee agreed that the licence should be varied to authorise the testing of embryos for Mucopolysaccharidosis III (MPS-III) Type B (OMIM #252920); MPS-III Type C (OMIM #252940); and MPS-III Type D (OMIM #252930) 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 14/09/2011

Anna Carragher (Chair)