HFEA Licence Committee Meeting

30 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0119 (Birmingham Womens 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:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Mair Crouch (lay)	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
- Annex to the PGD application form
- 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

Tabled Paper

- Genetic Alliance UK opinion
- Licence Committee minutes - 29 July 2010

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre has been licensed to perform PGD since 21 April 2010 and has recently started to test for conditions.

2. The Committee noted that MPS III type A had been licensed for treatment using PGD and adjourned briefly to receive the set of minutes of the licence committee which considered that condition.

3. 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'.

4. The Committee noted that PGD for Mucopolysaccharidosis III (MPS-III) Type B (OMIM #252920); MPS-III Type C (OMIM #252940); and MPS-III Type D (OMIM #252930) is 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 25% chance of the embryo having the abnormality.

5. The Committee was minded not to continue with its consideration of the application because it found no statement regarding penetrance in the paperwork. The Committee required such a statement in order to make an informed determination in respect of penetrance. The Committee reminded itself of 5.1 of the Explanatory Note For Licence Committee, as approved by the Authority, which states 'When considering the significance of risk, the Licence Committee will take into account the penetrance of the condition'. Furthermore, the Committee noted that the Peer Review form clearly seeks from the peer reviewer a brief and explicit statement about penetrance.

6. The Committee decided to adjourn determination of the application to request information regarding penetrance in relation to the condition and that the item should be considered again at the earliest opportunity after this information has been provided.

Signed D.A.D ... Date 13/07/2011

David Archard (Chair)