HFEA Licence Committee Meeting

21 February 2013

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

Minutes – Item 1

Centre 0102 (Guy's Hospital) – PGD for Multiple Epiphyseal Dysplasia Type 5 (MED5) OMIM #607078

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Rebekah Dundas (lay) Debbie Barber (professional) Jane Dibblin (lay) Andy Greenfield (lay)	Lauren Crawford Legal Adviser: Juliet Oliver, Field Fisher Waterhouse

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

- Cover sheet
- Executive Summary
- PGD Application form
- Tabled : 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

Discussion

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied that the Centre has 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 supporting documents with this application did not contain a Genetic Alliance Opinion. The Committee were satisfied that they had, in any event, sufficient information before them on which to make a decision.

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 Multiple Epiphyseal Dysplasia Type 5 (MED5) OMIM #607078 is caused by mutations in the MATN3 gene and is inherited in an autosomal dominant manner. There is therefore a 1 in 2 chance of the embryo being affected by this condition. Penetrance is noted by the perr Reviewer to be 100%.

5. The Committee noted that the condition is serious because the age of onset is variable but typically between 2 and 10 years of age. Surgery is usually required from a young age. X-rays reveal late ossifying, small irregular, mottled epiphyses with eventual osteoarthritis caused by the loss of articular cartilage in many joints. The condition is very variable but at the severe end of the spectrum bilateral hip replacements in early adult life may be required. Major surgery (for joint replacement) is often required.

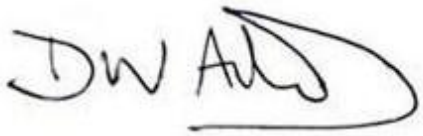
6. The Committee noted that those affected by this disorder suffer from progressive pain and stiffness in the joints, particularly the hips (sometimes as early as 5 years of age). The pain can be severe and lifelong. The Committee noted that there is no cure for this condition. Treatment involves pain management and frequently major surgery is required.

7. The Committee noted that the application is supported by the Peer Reviewer.

8. 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. The Committee was therefore satisfied that the condition meets the criteria for testing under paragraph 1ZA(1)(b) of Schedule 2 to the Act.

9. The Committee agreed to authorise the testing of embryos for Multiple Epiphyseal Dysplasia Type 5 (MED5) OMIM #607078. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 06/03/2013



David Archard (Chair)