HFEA Licence Committee Meeting

1 November 2012

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

Minutes – Item 3

Centre 0102 (Guy's Hospital) – PGD for Leber Congenital Amaurosis (OMIM #204000/ 204100)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay) Anna Carragher (lay) Mair Crouch (lay) – VC Rebekah Dundas (lay) – VC	Lauren Crawford 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

- Cover sheet
- Executive Summary
- PGD Application form
- Redacted Peer Review
- Genetic Alliance Opinion

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 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 Leber Congenital Amaurosis (OMIM #204000/ 204100) is a disorder that is inherited in an autosomal recessive manner. Therefore there is a 1 in 4 chance that an embryo will inherit the condition.

4. The Committee noted that symptoms result from poorly formed retinae and retinal degeneration. Leber Congenital Amaurosis is also associated with other vision signs including nystagmus (involuntary eye movement), sluggish or near-absent pupillary responses (pupils normally adjust to the amount of light), photophobia (extreme sensitivity to light), severe hyperopia (farsightedness) and keratoconus (abnormally shaped and thin cornea which causes substantial distortion of vision, with multiple images, streaking and sensitivity to light). Visual acuity is very poor and vision allows, at best, seeing light/dark or to detect some motion. Virtually all patients are registered blind.

5. The Committee noted that there is no curative treatment for Leber Congenital Amaurosis. Management is supportive; individuals may have correction of refractive errors and use of low vision aids. The life-long complete visual impairment reduces the quality of life, with difficulties at different levels: education, professional career and, in general, daily activities

6. The Committee considered the condition is serious because it is a very severe form of photoreceptor degeneration, with infants born blind or with a very limited visual function that worsens with age as a result of progressive retinal degeneration. This genetic condition is fully penetrant and has no cure, with

the consequent limitations in daily life activities, during the educational period and also in the professional career.

7. The Committee noted that the application is supported by the Peer Reviewer and the Genetic Alliance UK.

8. The Committee agreed to authorise the testing of embryos for Leber Congenital Amaurosis (OMIM #204000/ 204100)**.** The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 15/11/2012

David Archard (Chair)