HFEA Statutory Approvals Committee

27 June 2013

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

Minutes – Item 3

Centre 0102 (Guy's Hospital) – PGD application for Pontocerebellar Hypoplasia type 1B (PCH1B) OMIM #614678

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Lauren Crawford
Sue Price (professional)	
Rebekah Dundas (lay) (Videoconference)	Legal Adviser:
Debbie Barber (lay)	Stephen Hocking, DAC 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

- Cover sheet
- Executive Summary
- PGD Application form
- 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 that Pontocerebellar Hypoplasia type 1B (PCH1B) OMIM #614678 is inherited in an autosomal recessive pattern. There is therefore a 1 in 4 chance of the embryo being affected by this condition where both parents are carriers.

4. The Committee noted that PCH1B is an extremely rare disorder with fewer than 20 cases in medical literature.

5. The Committee noted that the disorder is fully penetrant.

6. The Committee noted that PCH1B is an abnormality of brain development. Babies with PCH1B are born floppy and unresponsive. They have difficulty sucking and swallowing. Many babies have sight problems, including blindness and involuntary eye movement. Babies' brains may grow slowly relative to their bodies (microcephaly).

7. The Committee noted that there is no cure for PCH1B. Babies may be kept alive with feeding directly to their stomach, and/or ventilator support.

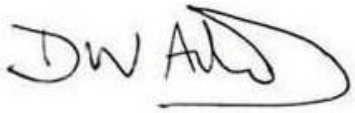
8. The Committee considered that the condition is serious because affected babies normally die in their first year of life due to inability to breathe.

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

10. 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.

11. The Committee agreed to authorise the testing of embryos for Pontocerebellar Hypoplasia type 1B (PCH1B) OMIM #614678. The Committee confirmed that this condition will be added to the published list of condition for which PGD may be carried out.

Signed: Date: 17/07/2013



David Archard (Chair)