HFEA Statutory Approvals Committee

24 April 2014

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

Minutes – Item 1

Centre 0119 (Birmingham Women's Hospital) – PGD application for CHARGE Syndrome OMIM #214800

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Sue Price (professional) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Peter Turnpenny	Committee Secretary: Lauren Crawford Legal Adviser: Graham Miles, Morgan Cole Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: The Members declared no conflicts in relation to this item

The following papers were considered by the Committee

- Executive summary
- 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) ("the Act")
- 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 proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, i.e. '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 CHARGE Syndrome (OMIM #214800) is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition in the few cases where one parent is affected.

4. The Committee noted that CHARGE Syndrome OMIM #214800 is the acronym given to the condition as it affects various parts of the body – Coloboma, Heart defect, Atresia choanae, Retarded growth and development, Genital abnormality, and Ear abnormality.

5. The Committee noted that the condition is variable and patients display a range of abnormalities with a number of life threatening conditions because of multiple congenital internal malformations. In the worst case scenario respiratory problems may be caused by a blockage of the nasal passage which can be fatal if not detected and treated at birth, and congenital heart defects which may be fatal as surgery may not be effective. Vision may be affected by coloboma, a gap in the structure in the eye; and retarded growth may cause continuing failure to thrive and severe learning disabilities.

6. The Committee noted this disorder is congenital and most cases are diagnosed at birth, although a few mildly affected individuals are diagnosed at a later date.

7. The Committee noted that the treatment options are as variable as the condition. The lack of hormones which stimulate the development of sexual organs at puberty may be managed medically and surgery can be used to manage physical effects of the condition, such as a cleft palate. Nasogastric feeding may be required for patients with swallowing problems, which persist throughout childhood. Other symptoms have no alleviating treatments available.

8. The Committee noted that the application is consistent with the Peer Review.

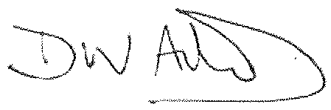
9. The Committee welcomed the advice of its Advisor, Peter Turnpenny, who confirmed that the condition was as described in the papers and is extremely variable and unpredictable within families.

10. The Committee considered that the condition is serious because it is a multiple congenital anomaly disorder with life-threatening symptoms which affects people from birth.

11. 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) and (2) of Schedule 2 to the Act.

12. The Committee agreed to authorise the testing of embryos for CHARGE Syndrome (OMIM #214800).

Signed: Date: 07/05/2014



David Archard (Chair)