Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
30 April 2015

Minutes – item 3

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for aniridia OMIM #106210

Members of the Committee	David Archard (Chair, lay) Sue Price (professional) Tony Rutherford (professional) Margaret Gilmore (lay)
Legal Adviser	Sarah Ellson, Fieldfisher
Specialist Attending	Dr Mary Porteous
Members of the Executive	Sam Hartley, Head of Governance and Licensing Trent Fisher, Secretary

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
- 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)
- HFEA decision trees

- 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

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 condition being applied for is not on the approved PGD condition list.

3. 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'.

4. The committee noted that aniridia OMIM #106210 is inherited in an autosomal dominant pattern and there is a 1 in 2 chance of an embryo being affected with the condition, where one parent is affected.

5. The committee noted that aniridia is a condition where an individual presents with a lack or reduced size of the iris. This can cause reduced vision to the individual being considered legally blind and development of glaucoma causing severe ocular pain.

6. The committee noted that other symptoms that may develop are uncontrollable movement of the eye, visually significant cataracts developing during teenage years or early adulthood, a reduced sense of smell and hearing impairments.

7. The committee noted that the condition is present from birth, demonstrates complete penetrance and is highly variable in severity.

8. The committee noted that there is no curative treatment for the condition and the only treatment options available are those to manage some of the symptoms that arise.

9. The committee noted that the application is consistent with the Peer Review.

10. The committee noted that the Genetic Alliance and Aniridia Network UK have submitted a joint opinion in support of PGD for aniridia OMIM #106210.

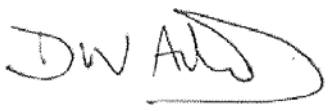
11. The committee welcomed the advice of its advisor, Dr Mary Porteous, who confirmed that the condition is as described in the papers and explained that this form of aniridia OMIM #106210 is caused by a PAX 6 mutation. In addition, Dr Porteous added that the treatment of glaucoma becomes extremely difficult due to the structure of the eye when this condition is present.

12. The committee considered that the condition is serious due to the onset of symptoms at birth, the complete penetrance and variability of the condition, the lack of curative treatment and the difficulty in treating the symptoms that arise.

13. The committee had regard to its decision tree and 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.

14. The committee agreed to authorise the testing of embryos for aniridia OMIM #106210.

Signed: Date: 12 May 2015



David Archard(Chair)