Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital) – PGD application for X-linked Ocular Albinism, OMIM #300500

Thursday, 28 April 2016

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

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anthony Rutherford Ruth Wilde Anne Lampe	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Mary Porteous	
Legal Adviser	Philip Grey	Mills & Reeve
Observers	None	

Declarations of interest:

- Mr Tony Rutherford declared a conflict of interest in relation to the application and withdrew from the meeting whilst the committee considered the application.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- executive summary
- PGD application form
- supporting research publication
- redacted peer review
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers adding that in the worst case scenario an individual's vision may be 6/60.

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

1.3. 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.

1.4. The committee noted that the condition being applied for is not on the approved PGD condition list.

1.5. 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'.

1.6. The committee noted that the condition is inherited in an x-linked pattern and there is a 1 in 4 chance of an embryo being affected with the condition where one parent is affected.

1.7. The committee noted that the condition is inherited in an X-linked pattern and there is a 1 in 2 chance of a male embryo being affected with the condition born to a female who is a carrier and a 1 in 2 chance of a female embryo being a carrier of the condition when inheriting the affected gene.

1.8. The committee noted that the condition affects an individual's eyes and manifests as reduced coloured pigment in the iris and retina. The condition impairs the sharpness of vision and the person's depth perception. Symptoms appear at birth, however they can improve during an infant's eye development. Once vision is stable it will not deteriorate.

1.9. The committee noted that other symptoms can include involuntary eye movements; eyes not looking in the same direction, an increased sensitivity to light and far or near sightedness which may involve astigmatism.

1.10. The committee noted that there is no curative treatment for the condition but treatment for some of the symptoms.

2. Decision

2.1. The committee considered that the condition is serious as in its worst case scenario an individual will have a significant visual impairment that will have a major impact on their quality of life.

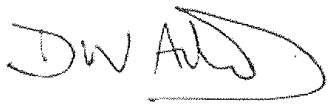
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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.

2.3. The committee agreed to authorise the testing of embryos for X-linked Ocular Albinism, OMIM #300500.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

David Archard

Date

13 May 2016