Statutory Approvals Committee - minutes

Centre 0201 (Edinburgh Assisted Conception Unit) – PGD application for Autosomal Dominant Retinitis Pigmentosa type 4 OMIM #613731

Thursday, 25 February 2016

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

Committee members	David Archard (Chair) Margaret Gilmore Anthony Rutherford Anne Lampe	
Members of the Executive	Trent Fisher	Secretary
External adviser	Professor John Walter	
Legal Adviser	Dawn Brathwaite	Mills & Reeve
Observers	None	

Declarations of interest:

- Dr Anne Lampe 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
- redacted peer review
- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor John Walter, who confirmed that the condition is as described in the papers.

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 autosomal dominant pattern which means there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected with this condition.

1.7. The committee noted that the condition is a degenerative eye condition which affects the retina resulting in early onset progressive vision loss.

1.8. The committee noted that symptoms include loss of peripheral vision. Gradually the progressive constriction of the field of vision can lead to tunnel vision. In some patients vision can further deteriorate and also affect residual central vision. The development of cataracts may also be a further complication. It is not unusual for individuals with this condition to be registered completely blind.

1.9. The committee noted that the condition demonstrates a complete penetrance and onset of symptoms can be from teenage years to early adulthood.

1.10. The committee noted that there is no curative treatment for the condition. Management options available for the condition include low vision aids and surgical treatment to remove cataracts.

2. Decision

2.1. The committee considered that the condition is serious due to early onset of vision loss with no curative treatment available.

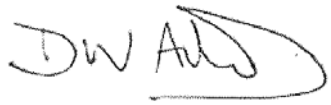
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Autosomal Dominant Retinitis Pigmentosa type 4 OMIM #613731

3. Chair's signature

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

Signature



Name

David Archard

Date

10/03/2016