Statutory Approvals Committee - minutes

Centre 0035 (Oxford Fertility) – PGD application for Peutz-Jeghers Syndrome OMIM #175200

Thursday, 29 September 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	David Archard (Chair) Rebekah Dundas (Deputy Chair) Margaret Gilmore Anne Lampe Ruth Wilde	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
External adviser	Jenny Carmichael	
Legal Adviser	Jane Williams	Mills & Reeve LLP
Observers	None	

Declarations of interest:

- members of the committee declared that they had no conflicts of interest in relation to this item.

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
- public comment

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Dr Jenny Carmichael, who confirmed that the condition is as described in the papers. Dr Carmichael informed the committee that individuals who inherit the condition will require regular cancer screening from 10 years of age.

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 and there is a 1 in 2 chance of an embryo being affected with the condition where one parent is affected.

1.7. The committee noted that the condition is characterised by the development of noncancerous growths (polyps) in the gastrointestinal tract.

1.8. The committee noted that the polyps frequently cause bowel obstructions, chronic bleeding and abdominal pain. Individuals also suffer from an increased risk of developing cancer, particularly that of the breast, ovary, pancreas, cervix and gastrointestinal tract.

1.9. The committee noted further that the mean age of individuals who go on to develop cancer is early 40s with nearly 50 per cent of affected individuals dying from cancer by 57 years of age.

1.10. The committee noted that the condition demonstrates complete penetrance. Onset of symptoms is during childhood to adolescence.

1.11. The committee noted that there is no curative treatment for the condition. Supportive treatment includes endoscopy or surgery to remove polyps and frequent screening for cancer.

2. Decision

2.1. The committee considered that the condition is serious due to high risk of cancer and severe symptoms that impact on the quality of life.

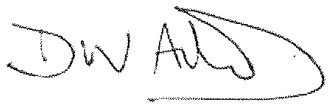
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious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

2.3. The committee agreed to authorise the testing of embryos for Peutz-Jeghers Syndrome OMIM #175200.

3. Chair's signature

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

Signature



Name

David Archard

Date

13 October 2016