Statutory Approvals Committee - minutes

Centre 0201 (Edinburgh Assisted Conception Unit) – PGD application for Axenfeld-Rieger syndrome types 1 & 3 OMIM #180500 #602482

Thursday, 31 March 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 Ian Brown	Secretary Head of Corporate Governance
External adviser	Alison Male	
Legal Adviser	Ros Foster	Browne Jacobson LLP
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, Dr Alison Male, 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 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 congenital eye abnormalities as well as congenital heart disease.

1.8. The committee noted that symptoms can include the development of a particularly severe form of glaucoma that may result in blindness and congenital heart disease which can be life threatening. Other symptoms that can develop include hearing loss, dental abnormalities and abnormalities of the belly button.

1.9. The committee noted that the condition demonstrates a high penetrance and onset of symptoms is variable and may be from infancy. The committee noted further that due to the variability of the condition, individuals will need lifelong monitoring.

1.10. The committee noted that there is no curative treatment for the condition. Treatment for the symptoms of the condition can cause further complications.

2. Decision

2.1. The committee considered the condition as serious due to the severity of symptoms that present, the risks associated with treatment of symptoms and the variability of the condition.

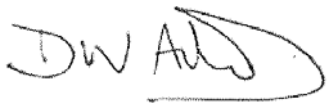
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Axenfeld-Rieger syndrome types 1 & 3 OMIM #180500 #602482.

3. Chair's signature

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

Signature



Name

David Archard

Date

14/04/2016