Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Oculocutaneous Albinism type 2 OMIM #203200

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:

- 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

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 recessive pattern and there is a 1 in 4 chance of an embryo being affected with the condition where both parents are carriers.

1.7. The committee noted that the condition is primarily characterised by the body's lack of ability to produce pigment. Individuals may present with white or translucent hair as well as pale skin.

1.8. The committee noted that symptoms include reduced visual acuity, rapid involuntary eye movements, and increased risk of developing skin cancer such as melanoma.

1.9. The committee noted that the condition demonstrates complete penetrance. Onset of symptoms are from infancy.

1.10. The committee noted that there is no curative treatment for the condition and that the only treatment options available are to treat some of the symptoms that present. Poor vision may impact on education and In some communities the pale skin of the condition exposes the sufferer to extreme stigmatisation and isolation.

2. Decision

2.1. The committee considered that the condition is serious due to significant visual impairment associated with the condition and the increased risk of developing melanoma.

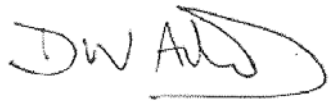
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Oculocutaneous Albinism type 2 OMIM #203200.

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