Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health) – PGD application for Amyotrophic Lateral Sclerosis Frontotemporal Dementia OMIM #105550

Thursday, 31 March 2016

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

Committee members	David Archard (Chair) Anne Lampe Margaret Gilmore Anthony Rutherford	
Members of the Executive	Trent Fisher Ian Brown	Secretary Head of Corporate Governance
External adviser	Dr 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 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 an adult onset neurodegenerative disorder and patients may present either predominantly with symptoms of Frontotemporal Dementia or with symptoms of Amyotrophic Lateral Sclerosis or with symptoms overlapping both conditions.

1.8. Individuals with Frontotemporal Dementia symptoms may undergo progressive changes in behaviour, decision making and language skills due to a loss of function in the neurons in the front and side sections of the brain. They may have a tendency to psychosis, hallucinations and psychiatric disturbances. This form of dementia may lead to socially inappropriate behaviour, impulsive tendencies, memory loss and a deteriorating ability to perform everyday tasks.

1.9. The committee noted that the Amyotrophic Lateral Sclerosis symptoms include muscle stiffness and weakness, fine muscle twitches, cramps and muscle shrinkage. On average individuals die within two to three years after being diagnosed with the condition.

1.10. The committee noted that penetrance is 50 percent for individuals aged 50 to 60 and that penetrance increases to 90 percent for individuals aged 70.

1.11. 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.

2. Decision

2.1. The committee considered that the condition is serious due to the severity of the symptoms that present and the high degree of penetrance.

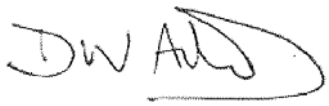
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Amyotrophic Lateral Sclerosis Frontotemporal Dementia OMIM #105550.

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