Statutory Approvals Committee - minutes

Centre 0044 (Centre for Reproductive and Genetic Health)

Pre-implantation Genetic Diagnosis (PGD) application for

Seizures, Cortical Blindness, Microcephaly Syndrome (SCBMS), OMIM #616632

Monday, 23 January 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser	Dr Ed Blair	
Legal Adviser	Tom Rider	Field Fisher
Observers	Bobby Farsides Bernice Ash	Member (Induction) Committee Secretary

Declarations of interest

- Members of the panel 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 adviser, Dr Ed Blair, who confirmed that the condition is as described in the papers.

1.2. The committee noted that the description in the PGD application for SCBMS is consistent with the Peer Review.

1.3. 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 list of approved PGD conditions.

1.5. The committee noted that SCBMS is a neurodevelopmental disorder (i.e. a disorder of brain function that affects emotion, learning ability, self-control and memory and that unfolds as the individual grows), characterized by the early onset of seizures at three to six months old, cortical blindness (ie: inability to see because of damage to the brain) and microcephaly (small head size). Other symptoms include severely delayed psychomotor development (includes skills that involve both mental and muscular activity, such as the ability of the infant to turn over, sit or crawl at will, walk, talk, control bladder and bowel functions and begin to solve cognitive problems). Individuals also tend to show poor overall growth and short stature.

1.6. The committee noted that there is no curative treatment for the condition.

1.7. The committee noted the inspectorate's recommendation to consider the approval of Seizures, Cortical Blindness, Microcephaly Syndrome (SCBMS), OMIM #616632.

2. Decision

2.1. The committee had regard to its decision tree.

2.2. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph IZA(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'.

2.3. 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 parent are carriers of relevant mutations.

2.4. The committee noted that the condition demonstrates 100% penetrance and the onset of symptoms is at birth.

2.5. The committee considered that the condition is serious due to the severe developmental delay, cortical blindness, seizure disorder associated with it. The committee also considered the poor quality of life and short life expectancy of an affected child and the effect on the family caring for a child with this condition.

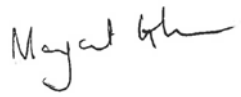
2.6. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition meets the criteria for testing under paragraph IZA(1)(b) and (2) of Schedule 2 of the Act.

2.7. The committee agreed to authorise the testing of embryos for Seizures, Cortical Blindness, Microcephaly Syndrome (SCBMS), OMIM #616632.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

10 February 2017