Human Fertilisation and Embryology Authority

Minutes of the Statutory Approvals Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
30 July 2015

Minutes – item 4

Centre 0101 (CARE Nottingham) – PGD application for Christianson syndrome OMIM #300243

Members of the Committee	David Archard (Chair, lay) Rebekah Dundas (Deputy Chair, lay) Sue Price (professional) Margaret Gilmore (lay) Bishop Lee Rayfield (lay)
Legal Adviser	Jane Williams, Mills & Reeve
Specialist Attending	Professor John Walter
Members of the Executive	Trent Fisher, Secretary

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

The following papers were considered by the committee:

- executive summary
- PGD application form
- redacted peer review
- Genetic Alliance opinion

The committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA decision trees
- guidance for members of Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- guidance on periods for which new or renewed licences should be granted

- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- guide to licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Discussion

1. 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.

2. The committee noted that the condition being applied for is not on the approved PGD condition list.

3. 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'.

4. The committee noted that Christianson syndrome OMIM #300243 is inherited in an X-linked recessive pattern and there is a 1 in 2 chance of a female embryo being a carrier and a 1 in 2 chance of a male embryo being affected with the condition where the mother is a carrier.

5. The committee noted that, because this is an X-linked condition, all male embryos that inherit the condition will present with symptoms. There is some evidence that female carriers may also exhibit learning difficulties and be at risk of neurological problems later in life.

6. The committee noted that the condition is a neurological degenerative disorder that causes severe learning disabilities. Symptoms may include profound intellectual disabilities, delayed motor development and recurrent seizures. There is some evidence to suggest that lifespan is shortened.

7. The committee noted that other symptoms that may present include poor coordination, difficulties standing and walking, and abnormal eye movements.

8. The committee noted that the condition demonstrates complete penetrance and that symptoms in males will be present from birth; in females, the condition may manifest itself much later.

9. The committee noted that there is no curative treatment for the condition and the only treatment options available are those to manage the symptoms that arise from the condition.

10. The committee noted that the application is consistent with the Peer Review.

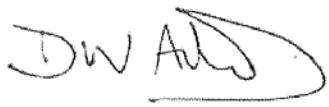
11. The committee welcomed the advice of its Advisor, Professor John Walter, who confirmed that the condition is as described in the papers, adding that it is a severe neurological degenerative disorder.

12. The committee considered that the condition is serious due to the severity of the symptoms that present from birth and the lack of any curative treatment.

13. 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.

14. The committee agreed to authorise the testing of embryos for Christianson syndrome OMIM #300243.

Signed: Date: 12 August 2015



David Archard(Chair)