HFEA Statutory Approvals Committee

20 November 2014

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

Minutes – Item 1

Centre 0102 (Guys Hospital) – PGD application for Retinitis Pigmentosa 7 OMIM #608133

Members of the Committee: David Archard (lay) Chair Rebekah Dundas (lay) Jane Dibblin (lay) Debbie Barber (professional) Advisor: Dr Anne Lampe	Committee Secretary: Trent Fisher Legal Adviser: Ros Foster, Browne Jacobson Also in attendance: Sam Hartley, Head of Governance and Licensing, HFEA

Declarations of Interest: The Members declared no conflicts in relation to this item

The following papers were considered by the Committee:

- Application form
- Executive summary
- Further information from centre
- Redacted peer review
- Clarification email from the centre
- Further information from peer reviewer
- 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) ("the Act")
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- 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
- HFEA Pre-Implantation Diagnostic Testing ("PGD") Explanatory Note For Licence Committee

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 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'.

3. The Committee noted that Retinitis Pigmentosa 7 (OMIM#608133) 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.

4. The Committee noted that affected individuals may initially find it difficult to see in dim light or at night. In addition reduced peripheral vision may progress to tunnel vision and the individual becoming registered blind. Some affected individuals may also develop cataracts and/or macular oedema.

5. The Committee noted that the onset of symptoms can be from childhood with a majority of individuals reporting some loss of vision by early adulthood.

6. The Committee noted that currently there is no curative treatment for Retinitis Pigmentosa 7 although the effects of photophobia and cataracts can be managed. Visual loss and blindness can have an impact on education, employment, lifestyle and driving, depending on the extent of visual loss and the age at which symptoms occur.

7. The Committee noted that the application is consistent with the Peer Review.

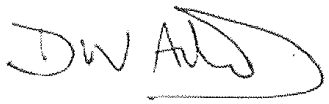
8. The Committee welcomed the advice of its Advisor, Dr Anne Lampe, who confirmed that the condition was as described in the papers.

9. The Committee considered that the condition is serious because it is an incurable condition that, taken in its worst form of blindness, would have a profound effect on the patient's quality of life.

10. 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.

11. The Committee agreed to authorise the testing of embryos for Retinitis Pigmentosa 7 (OMIM #608133).

Signed: Date: 4 December 2014



David Archard (Chair)