HFEA Statutory Approvals Committee

24 October 2013

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

Minutes – Item 1

Centre 0035 (Oxford Fertility Unit) – PGD application for Alport's Syndrome (Autosomal Dominant) OMIM #104200

Members of the Committee: David Archard (lay) Chair Sue Price (professional) Jane Dibblin (lay) Hossam Abdalla (professional) Apologies: Debbie Barber (professional) Rebekah Dundas (lay)	Committee Secretary: Lauren Crawford Legal Adviser: Tom Rider, Field Fisher Waterhouse Observing: Sam Hartley, Head of Governance and Licensing, HFEA Juliet Tizzard, Interim Director of Strategy, HFEA

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

The following papers were considered by the Committee

- Executive Summary
- PGD Application Form
- 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)
- 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 this genetic type of Alport's Syndrome (OMIM #104200) is inherited in an autosomal dominant pattern. There is therefore a 1 in 2 chance of the embryo being affected by this condition where a parent is affected.

4. The Committee noted that Alport's Syndrome is a genetic condition characterised by kidney disease, hearing loss, and eye abnormalities. People with Alport's Syndrome experience progressive loss of kidney function. Almost all affected individuals have blood in their urine (hematuria), which indicates abnormal functioning of the kidneys. Many people with Alport's Syndrome also develop high levels of protein in their urine (proteinuria). The kidneys become less able to function as this condition progresses, resulting in end-stage renal disease (ESRD).

5. The Committee noted that the age of onset is extremely variable but in a worst case scenario, symptoms can develop in childhood.

6. The Committee noted that current treatment options for Alport's Syndrome are mainly focused on replacing the kidney function with regular dialysis or a kidney transplant, each with associated risks.

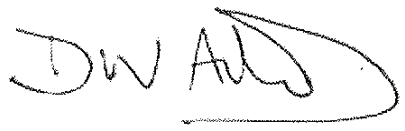
7. The Committee considered that the condition is serious because affected children develop serious symptoms in early childhood and would need to undergo major and invasive surgery at a young age if organs were available. Most affected individuals will suffer some form of kidney dysfunction which can result in renal failure, which is a major cause of death in this condition.

8. The Committee noted that the application is supported by the Genetic Alliance UK.

9. 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) of Schedule 2 to the Act.

10. The Committee agreed to authorise the testing of embryos for Alport's Syndrome (OMIM #104200).

Signed: Date: 04/11/2013



David Archard (Chair)