HFEA Statutory Approvals Committee

25 September 2014

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

Minutes – Item 5

Centre 0035 (Oxford Fertility Unit) – PGD application for Juvenile Polyposis Syndrome (OMIM #174900)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair	Sam Hartley, Head of Governance and Licensing
Rebekah Dundas (lay)	
Jane Dibblin (lay)	
Hossam Abdalla (professional)	Legal Adviser:
	Dawn Brathwaite, Mills & Reeve
Advisor:	
Dr Edward Blair	

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
- Redacted Peer Review form
- Genetic Alliance opinion
- Licence Committee minutes from 24/06/2010 meeting regarding PGD application for BRAC2 OMIM #61255/600185

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 Juvenile Polyposis Syndrome (OMIM #174900) 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 juvenile polyposis syndrome is characterised by multiple growths called polyps. These growths typically occur in the large intestine (colon), and the number of polyps can vary from only a few to hundreds even among affected members of the same family. Polyps may cause gastrointestinal bleeding, a shortage of red blood cells (anaemia), abdominal pain and diarrhoea. Most juvenile polyps are benign (noncancerous), but there is a chance that polyps can become malignant (cancerous).

5. The Committee noted that typically symptoms start around 20 years of age, however for juvenile polyposis of infancy symptoms present during childhood.

6. The Committee noted that there is no curative treatment available for this condition.

7. The Committee welcomed the advice of its advisor, Dr Edward Blair. Dr Blair clarified the clinical description of the condition as detailed in the papers. He advised that the Committee should be clear in its mind that it was only

considering the authorisation of Juvenile Polyposis Syndrome caused by mutations in the SMAD4 or BMPR1A genes (OMIM #174900), and advised that some of the description in the paperwork conflated the condition with that caused by mutations in the PTEN gene (e.g. Cowden disease). The Committee accepted Dr Blair's advice.

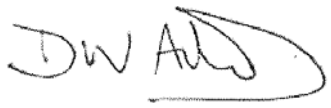
8. The Committee noted the responses from the Peer reviewer and also noted that this application is supported by the Genetic Alliance. The Committee noted that Executive had included a previous set of minutes relating to BRAC2 OMIM #61255/600185. The Committee agreed that these minutes were not relevant and excluded them from its consideration.

9. The Committee considered that the condition is serious due to the severe effect on the quality of life of patients, particularly children, caused by the clinical manifestations and interventions required. It was further concerned over the stated raised risk of developing colorectal cancer.

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 Juvenile Polyposis Syndrome caused by mutations in the SMAD4 or BMPR1A genes (OMIM #174900).

Signed: Date: 07/10/2014



David Archard (Chair)