HFEA Licence Committee Meeting

24 June 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0044 Centre for Reproductive and Genetic Health (CRGH) – Variation application to perform PGD for Breast Ovarian Cancer Familial Susceptibility (BRCA2), OMIM# 61255/600185

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (lay) Sally Cheshire (lay) Jane Dibblin (lay) Sue Price (Professional)	Terence Dourado Legal Adviser: Rosalind Bedward

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
- Signed application form (including any appendices)
- Redacted peer review
- Additional communication from nurse specialist at Centre 0044 establishing that the BRCA2 gene had been confirmed as pathogenic.

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

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre already has considerable experience of carrying out PGD and had conducted 37 PGD cycles between 1 January 2009 and an interim inspection at the Centre on 5 November 2009.

2. The Committee noted that the Centre's proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of schedule 2 of the Act, ie. '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 form of Breast Ovarian Cancer Familial Susceptibility (BRCA2) is inherited in an autosomal dominant inheritance pattern, i.e. only one copy of the affected gene is needed to cause the disorder. And there is a 50% chance of the embryo inheriting the affected gene.

4. The Committee noted that there is a significant risk because women with an inherited mutation in BRCA2 have a 79.5% risk of developing breast cancer by age 70. Male carriers of a BRCA2 mutation have an estimated lifetime risk of 6.3% of developing breast cancer, which is higher than the general population.

5. The Committee noted that the condition is serious because susceptibility to breast and ovarian cancer is caused by heterozygous BRCA2 mutations, transmitted in an autosomal dominant fashion. The treatment for breast cancer may be hormonal therapy, chemotherapy, radiotherapy and or surgery. The prognosis depends on variable factors, such as staging, tumour size and location. Younger women tend to have a poorer prognosis than post-menopausal women. Additionally, the emotional impact of breast cancer diagnosis, treatment, and related issues can be severe.

6. On the basis of the information presented, the Committee 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. Accordingly, it was appropriate to grant the application under 1ZA(1)(b) of Schedule 2 to the Act.

7. The Committee agreed that the licence should be varied to authorise the testing of embryos for Breast Ovarian Cancer Familial Susceptibility (BRCA2), OMIM# 61255/600185, and that no conditions should be put on the licence in relation to the variation. The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed..... Date...9/7/2010..

David Archard (Chair)