HFEA Licence Committee Meeting

28 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0201 (Edinburgh Assisted Conception Unit) – Application to perform PGD for Autosomal Dominant Retinitis Pigmentosa OMIM# 604485

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Rebekah Dundas (lay) Sue Price (professional)	Terence Dourado Legal Advisers: Graham Miles, Morgan Cole

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
- Anonymised peer review
- Opinion from the Genetic Alliance

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 has been licensed to provide PGD since 12 August 2009 and that genetic testing was provided by an NHS laboratory with considerable experience notably in the area of pre-natal screening.

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 Autosomal Dominant Retinitis Pigmentosa OMIM #604485 is inherited in an autosomal dominant manner. Only one copy of the affected gene is required to cause the disorder, i.e. there is a 50% chance of the embryo being affected in a family where one parent is affected and the other is unaffected.

4. The Committee considered that the condition is serious because the particular mutation has been associated with an early onset of clinical symptoms in affected individuals. Night blindness is followed by progressive central visual loss resulting in near or complete blindness. It is reported that night blindness occurs as early as six years of age with functional blindness occurring by mid-twenties. However, the phenotype for the condition is variable and the onset may be later and the progression slower. There is currently no treatment to reverse or halt progression of visual loss. The Committee noted that in an individual inherits the NR2E3 Gly56Arg mutation he or she will develop the condition, usually with recognisable symptoms, by the age of twenty years.

5. 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.

6. The Committee agreed that the licence should be varied to authorise the testing of embryos for Autosomal Dominant Retinitis Pigmentosa OMIM #604485, 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 D.A. ..... Date 9.11.2010

David Archard (Chair)