HFEA Licence Committee Meeting

25 February 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0101 (CARE Nottingham) – Variation application to perform PGD for Acute Intermittent Porphyria, OMIM# 176000

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Anna Carragher (lay) Rebekah Dundas (lay) Sue Price (Professional)	Terence Dourado
Apologies: Jane Dibblin (lay)	Legal Advisers: 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
- Application form
- Anonymised peer review
- Email response from centre to peer review question
- Email from peer reviewer supporting the application

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 Acute Intermittent Porphyria is inherited in an autosomal dominant inheritance pattern. Therefore only one copy of the affected gene is needed to cause the disorder. In this type of inheritance there is a 50% chance of the embryo inheriting the affected gene.

4. The Committee noted that there is a significant risk that those born with the affected gene will develop an abnormality because the penetrance of the condition is variable and can be up to 52%.The Committee noted that the condition usually presents past puberty, is life threatening and potentially fatal. Treatment is mainly supportive and there is no reliable cure for the condition.

5. The Committee noted that the condition is serious because it is a potentially severe and debilitating form of Porphyria; a group of metabolic disorders due to a deficiency in the enzymes involved in haem synthesis. The enzyme deficiency results in the overproduction and increased excretion of toxic haem precursors that are formed prior to the enzyme defect. People with Acute Intermittent Porphyria experience episodes of pain and disruption of the nervous system that may develop rapidly and severely, causing a wide range of symptoms throughout the body. The symptoms include abdominal pain, nausea, vomiting and constipation, pain and muscle weakness. In extreme cases symptoms can include heart

palpitations and rapid heartbeat, high blood pressure, anxiety, confusion, seizures and paralysis and death. There is also an increased risk of developing hepatocellular carcinoma and renal insufficiency has been reported. The Committee acknowledged that at its worst the implications of the condition can have devastating effects on the quality of life both mentally and physically.

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 Acute Intermittent Porphyria, OMIM# 176000 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...5/3/2010

David Archard (Chair)