HFEA Licence Committee Meeting

25 March 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 7

Centre 0044 (Centre for Reproductive and Genetic Health) – Variation application to perform PGD for Stuve-Wiedemann Syndrome, OMIM# 601559

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair 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
- Signed application form (including appendix)
- Redacted peer review

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 46 PGD cycles between 1 January 2008 and 31 December 2009.

2. The Committee noted that the purpose of testing the embryos was set out in paragraph 1ZA(1)(a) 'establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth; or 1ZA(1)(b) '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 Stuve-Wiedemann Syndrome is inherited in an autosomal recessive pattern. If an embryo inherits a copy of the faulty gene from both parents it will develop the disease, ie. there is a 25% chance of the embryo having the abnormality.

4. The Committee noted that there is a significant risk that those born with the affected gene will develop an abnormality because it is 100% penetrant.

5. The Committee noted that the condition is serious because it is congenital and life threatening; commonly causing death in infancy. The condition is rare and is characterised by significant skeletal abnormalities, short stature, bowed long bones in the arms and legs, and permanent flexed fingers and toes. A baby with the condition may endure life-threatening complications such as very high temperatures and pneumonia leading to death within its first 18 months. It may also endure sweating when cold but not when hot due to an abnormal autonomic nervous system. Treatment for the condition is supportive but not curative with patients needing physiotherapy and/ or surgery for bone abnormalities. The condition has little phenotypic variation.

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. Having granted the application under 1ZA(1)(b) the Committee did not need to make a determination under 1ZA(1)(a).

8. The Committee agreed that the licence should be varied to authorise the testing of embryos for Stuve-Wiedemann Syndrome, OMIM# 601559 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. 31/03/2010..

David Archard (Chair)