HFEA Licence Committee Meeting

30 June 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0102 (Guy's Hospital) – PGD for Amyotrophic Lateral Sclerosis 1 (ALS1) OMIM# 105400

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Mair Crouch (lay) Rebekah Dundas (lay) (via videoconference)	Terence Dourado Legal Adviser: 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
- Redacted peer review
- Centre's response to 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
- HFEA Pre-Implantation Diagnostic Testing (“PGD”) Explanatory Note For Licence Committee

Tabled Papers

- Genetic Alliance UK opinion

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the Centre has considerable 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 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 Amyotrophic Laterals Sclerosis 1 (ALS1) OMIM# 105400 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 noted that there is a significant risk that a person with the abnormality will develop a serious medical condition because it is highly penetrant; 90% of those with the mutation will develop the condition by 70 years of age.

5. The Committee noted that the condition is the most common form of motor neurone disease. It considered that the condition is serious because it is a rapidly progressive neurodegenerative condition characterised by progressive muscular paralysis, affecting the limbs and respiratory muscles. It can sometimes be accompanied by fronto-temporal dementia. The Committee considered that there is no effective treatment for the condition and death due to respiratory failure generally occurs under five years after the onset of symptoms. The average age of onset of ALS1 is 46 years.

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 paragraph 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 Amyotrophic Lateral Sclerosis 1 (ALS1) OMIM# 105400 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 13/7/2011

David Archard (Chair)