HFEA Licence Committee Meeting

26 January 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 3

Centre 0201 (Assisted Conception Unit, Edinburgh) – PGD for Charcot Marie Tooth Disease Type 2 (OMIM #609260)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Sue Price (professional) Debbie Barber (professional) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Graham Miles, Field Fisher Waterhouse

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

- Cover sheet
- Executive Summary
- PGD Application form
- Additional Information (Email)
- Supporting Journal Article – Verhoeven et al (2006)
- Redacted Peer Review
- Genetic Alliance opinion

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

Background

1. The Committee had regard to its Decision Tree. The Committee noted that the Centre is licensed to carry out PGD. The Committee was also satisfied 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 Charcot Marie Tooth Disease Type 2 (OMIM #609260) is an autosomal dominant condition caused by an embryo inheriting a mutated copy of the MFN2 gene. There is a 1 in 2 chance of an embryo inheriting a mutated MFN2 gene if one of the parents is affected. Charcot Marie Tooth Disease Type 2 is an inherited neuropathy that is predominantly characterised by loss of sensation and position sense with loss of muscle power.

4. The Committee noted that there is no specific treatment for Charcot Marie Tooth Disease Type 2. The presenting features are usually weakness of the lower limbs particularly affecting the feet and ankles. Progressive weakness of the lower limbs lead to problems with mobility and a small portion of affected individuals ultimately require wheelchair support.

5. The Committee noted the variability in expression of the phenotype between families and the fact that the gene can also be recessively inherited.

The age of onset is variable but usually within the first or second decades of life.

6. The Committee considered that at its most sever the condition is serious because some affected individuals will be dependent on crutches or a wheelchair in adult life and when arms are also involved, individuals may find everyday tasks difficult due to weakness. The affected individual is often managed by a multidisciplinary team that includes a neurologist, orthapaedic surgeon, orthotist and occupational therapists. There is no curative treatment and therapy is aimed at minimising symptoms for example treatment of musculoskeletal pain with nonsteroidal anti-inflammatory agents and treatment of neuropathic pain with tricyclic antidepressants, and the use of orthotic splints to maintain joint stability for mobility due to muscle weakness.

7. The Committee noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK.

8. The Committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it 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.

9. The Committee also noted section 5.5: Where a condition has variable symptoms, the Licence Committee will base its determination of how serious the disability, illness or condition is, on the worst possible symptoms.

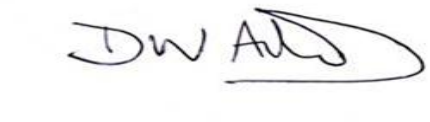
10. The Committee were satisfied that based on the information provided in the papers that Charcot Marie Tooth Disease Type 2 at the most severe end and presenting the worst symptoms of the disease, meets the statutory criteria for risk of seriousness necessary to authorise the undertaking of PGD for Charcot Marie Tooth Disease Type 2.

11. The Committee agreed to authorise the testing of embryos for Charcot Marie Tooth Disease Type 2 (OMIM #609260). The Committee confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

12. The Committee noted that although it was granting approval, the centre providing PGD for the condition must also ensure that each individual case

treated fulfils the severity criteria of Schedule 2 Paragraph 1ZA of the HFE Act 1990 (as amended).

Signed: Date: 20/02/2012



David Archard (Chair)