HFEA Licence Committee Meeting

25 February 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 7

Centre 0044 Centre for Reproductive and Genetic Health – Variation application to perform PGD for Central Core Disease of Muscle - OMIM# 117000

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
- 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 had considerable experience of carrying out PGD and had conducted 46 PGD cycles between 1 January 2008 and 31 December 2009. Additionally, the Centre was CPA accredited in accordance with standards for the medical laboratory incorporating ISO 15189:2007 in December 2009.

2. The Committee decided to consider the application on the assumption that the purpose of testing the embryos had only been 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'; notwithstanding the fact that the application also specified that the purpose of testing the embryos was as set out in paragraph 1ZA(1)(a) of schedule 2 of the Act, ie. 'establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth'.

3. The Committee began to consider the application but decided to adjourn as it was unable to make a decision due to the insufficient evidence put before it; particularly in respect of the seriousness of the condition. The Committee also noted that the peer reviewer had been unable to give a definitive view as to the significance of the risk that a person with the abnormality would develop a serious physical or mental disability, serious illness or other serious medical condition.

4. The Committee adjourned consideration of the item for receipt of further information from a specialist in managing patients with these types of disorders as to the significance of the risk and the seriousness of the condition.

5. In adjourning the application the Committee also wished to give the PR an opportunity to clarify whether they had intended to apply under 1ZA(1)(a) of schedule 2 of the Act.

Signed D.M. ..... Date 5/3/2010

David Archard (Chair)