HFEA Licence Committee Meeting

25 November 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0102 (Guys Hospital) – PGD for Simpson Golabi Behmel Syndrome Type 1 OMIM# 312870

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Debbie Barber (professional) Anna Carragher (lay) Sally Cheshire (lay) Mair Crouch (lay) Jane Dibblin (lay) Rebekah Dundas (lay) Sue Price (professional)	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:

- Licence Committee minutes – 28th October 2010
- Letter from the Centre's PR to the Chair of the licence committee
- Email from the Centre's inspector to the LC secretary

Submitted to the LC on 28th October 2010:

- Executive Summary
- PGD application form
- Redacted peer review
- Genetic Alliance UK 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

1. The Committee had regard to its Decision Tree and was satisfied that the Centre has an established PGD programme and has considerable experience of carrying out PGD.

2. The Committee, which met on 28th October 2010, requested clarification from the Centre about its proposed purpose of testing an embryo for Simpson Golabi Behmel Syndrome Type 1 (OMIM # 312870). The Committee minutes of that meeting informed the Centre of the following legal advice: "under paragraph 1ZA (1) of Schedule 2 to the Act a licence can authorise the testing of an embryo for one or more of the purposes set out in sub paragraphs (a) to (e). Accordingly, if the purpose set out in 1ZA (1) (b) applied, authorisation could be given even though testing would not also be for the purpose set out in 1ZA (1) (C). However, before testing could be authorised for the purpose set out in 1ZA (1) (b) the Committee had to be satisfied, in relation to the abnormality concerned, that 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. If the Committee was of the view that this statutory test would only be satisfied in relation to male rather than female embryos, consideration could be given to whether it would be appropriate to limit the scope of any authorisation given."

3. Having since received clarification from the Centre regarding its proposed purpose of testing, the Committee was satisfied that the Centre did not have a declared intention to select on sex alone. The Centre confirmed that its PGD test would detect four possible embryo genotypes: affected males; unaffected males; unaffected non-carrier females, and; carrier females. It confirmed that, aside from affected male embryos, all would be considered suitable for embryo transfer.

4. The Committee was satisfied that the application was made under the proposed purpose of testing the embryos 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'.

5. The Committee considered that the condition is inherited in an X-linked autosomal recessive manner. Males with the mutation will be affected, while females with the condition will be carriers (although some females may exhibit milder features of the condition).

6. The Committee considered that there is a significant risk that a male with the abnormality will develop a serious medical condition because the condition is 100% penetrant in males.

7. The Committee considered that the condition is serious because affected individuals with the condition are considerably larger than normal at birth and continue to grow and to gain weight at an unusual rate. Those with the condition are born with a number of abnormalities which can affect most of the major internal organs (including the heart), and the skeletal system. Hernias, genital abnormalities, broad features, and coarse facial features (abnormalities of the ears, eyes, nose, mouth and teeth) are common. As the condition is an overgrowth syndrome, affected individuals are at an increased risk of developing certain tumours. Intellectual problems are also common.

8. On the basis of the information presented, the Committee was satisfied that there is a significant risk that a male 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.

9. The Committee agreed that the licence should be varied to authorise the testing of embryos for Simpson Golabi Behmel Syndrome Type 1 OMIM# 312870 (with sex selection for males only). It confirmed that this condition will be added to the published list of conditions for which PGD may be carried out.

Signed..... Date.16/12/2010

David Archard (Chair)