HFEA Licence Committee Meeting

1st December 2011

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

Minutes – Item 2

Centre 0102 (Guys Hospital) – PGD for Dyskeratosis congenita (OMIM #305000)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Sally Cheshire (lay) (videoconference) Rebekah Dundas (lay) (videoconference) Sue Price (professional) Mair Crouch (lay) Jane Dibblin (lay)	Lauren Crawford Legal Adviser: Tom Rider, 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
- 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 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 Dyskeratosis congenita (OMIM #305000) is a disorder that is inherited in an X-linked manner. The overall embryo risk is 1 in 4 for an affected male. The risk for a male embryo is 1 in 2, and 1 in 2 female embryos will be carriers of the genetic change.

4. The Committee considered that there is a significant risk that a male person with the abnormality will develop a serious medical condition because it is fully penetrant in affected males.

5. The Committee considered that the condition is serious because Dyskeratosis congenita is a premature ageing condition defined by the triad of abnormal skin pigmentation, nail dystrophy, and leukoplakia of the oral mucosa, which undergoes malignant change. Progressive bone marrow failure occurs in over 80% of affected individuals and is the main cause of early mortality, with death typically occurring during childhood or teens. Bone marrow transplant therapy has been tried, but with poor outcome. Other manifestations of the condition include pulmonary fibrosis, liver cirrhosis, osteoporosis, learning difficulties and deafness together with a predisposition to a wide range of malignancies.

6. 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 male 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 noted that the application is supported by the Peer Reviewer as well as by Genetic Alliance UK.

8. The Committee noted that although the papers contained reference to female carriers showing features of the condition, it was not satisfied that it had sufficient information to license the testing of this condition on female embryos.

9. The Committee agreed to authorise the testing of male embryos for Dyskeratosis congenita (OMIM #305000). The Committee confirmed that this authorisation will be added to the published list of conditions for which PGD may be carried out.

Signed: Date: 12/12/2011

David Archard (Chair)