HFEA Licence Committee Meeting

1 March 2012

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

Minutes – Item 6

Centre 0017 (Newcastle Fertility Centre at Life) – PGD for Kearns Sayre Syndrome (KSS)/ Pearsons Marrow-Pancreas (PMPS) (OMIM #530000 &557000)

Members of the Committee:	Committee Secretary:
David Archard (lay) Chair Anna Carragher (lay) Rebekah Dundas (lay) (videoconference) Mair Crouch (lay) (videoconference) Sue Price (professional) 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 was satisfied that the Centre is licensed and has considerable experience of carrying 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 Kearns Sayre Syndrome (KSS)/ Pearsons Marrow-Pancreas (PMPS) (OMIM #530000 & 557000) are rare disorders caused by the same molecular change; a large-scale single deletion in mitochondrial DNA (mtDNA). The risk of inheriting of the deletion is estimated at 1 in 24.

4. The Committee noted that the Peer Reviewer states that 'If the embryo contains the mtDNA rearrangement at a high level then there is a high risk of the embryo inheriting the abnormality', but also comments on the wide variability in the severity of the symptoms. In addition, the Committee noted the observation of the Peer Reviewer that "In assessing the recurrence risk it is important to determine whether the diagnostic unit has tested for duplications and higher order rearrangements as this significantly increases the recurrence risk…Most diagnostic centres do not routinely do digests that are able to distinguish".

5. The Committee was minded to defer its consideration of the application for the following reasons:

- No clear recommendation from the Peer Reviewer and concerns expressed by the Peer Reviewer.
- No clear statement by the Centre or Peer Reviewer on degree of penetrance and any additional factors that may affect this in specific families.
- Insufficient information on the seriousness of the condition and the particular risk of an embryo having an abnormality.
- Insufficient assurances that other centres within the UK that would be licensed to carry out PGD for this condition would be qualified and competent to do so.

6. The Committee noted that it required such information in order to make a fully informed determination in respect of penetrance and risk. The Committee reminded itself of sections 4.2 and 5.1 of the Explanatory Note for Licence Committee, as approved by the Authority, which states 'When considering whether or not there is a particular risk that an embryo may have an abnormality, the Licence Committee will take into account whether or not the abnormality is heritable and if so, what the mode of inheritance is' and 'When considering the significance of risk, the Licence Committee will take into account the penetrance of the condition'. Furthermore, the Committee noted that the Peer Review form clearly seeks from the peer reviewer a brief and explicit statement about penetrance.

7. The Committee decided to adjourn determination of the application to request information on the matters set out in paragraph 5 and that the item should be considered at the earliest opportunity once this information has been provided.

Signed: Date: 09/03/2012

David Archard (Chair)