HFEA Licence Committee Meeting

15 October 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0102 (Guys Hospital) – Variation to include PGD for recurrent digynic triploidy.

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Anna Carragher (lay) Jane Dibblin (lay) Sue Price (clinician) Rebekah Dundas (lay) – by videolink	Rachel Fowler Legal Advisers: Graham Miles, Morgan Cole
Apologies: Sally Cheshire (lay)	

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
- PGD application
- Appendix to the application form: specific patient information
- Associated correspondence
- 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)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889); and
- 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.

1. The Committee considered the papers and noted that the relatively high rate of false positives when testing for recurrent triploidy, as stated in paragraph 4.6.2.1of the application, was to be expected given the proposed testing technique. The Committee also noted that this was the simples technique to detect triploidy. A member of the Committee also confirmed for other members that there was no OMIM number available for the condition. The Committee agreed that they were content with the information provided and would proceed with the PGD decision tree.

2. The Committee noted section 3.1 of the Executive Summary which set out the purpose of the test as being to establish whether the embryo is at risk of having three copies of every autosome and an XXX/XXY sex chromosome complement. The Committee were satisfied that the purpose of the test had been established.

3. The Committee noted section 4 of the Application which stated that Dygynic triploid conceptions typically abort spontaneously around 10 weeks gestation but some may continue into the third trimester of pregnancy. The Committee also noted the opinion of the Peer Reviewer that, in cases of recurrent digynic triploidy, the anomaly is attributable to a unique mechanism, likely to be genetic which is affecting oogenesis.

4. The Committee noted section 1.1 of the Executive Summary which stated that Centre 0102 had considerable experience of carrying out PGD and had conducted 143 fresh PGD cycles between 01/04/02008 and 31/03/32009.

<u>The Committee's Decision</u>

5. The Committee was satisfied that the purpose of the test falls within paragraph 1ZA(1)(a) of schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended). That purpose being, to establish whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth.

6. The Committee was also satisfied that this was a practice designed to secure that embryos were in a suitable condition to be placed in a woman within paragraph 1(1)(d) of Schedule 2. Further, the Committee agreed that, taking into account all the maters set out above, this practice was necessary and desirable for the purposes of providing treatment services, as required by paragraph 1(3) of Schedule 2.

7. The Committee decided to vary the Centre's licence to add PGD for Recurrent dygynic triploidy. The Committee were satisfied that no conditions should be placed on the PGD licence.

8. In making this decision, the Committee was aware that the condition will be published on the HFEA website and all centres licensed to perform PGD will be able to perform PGD to test for this condition. The Committee wished to stress that the condition authorised is **Recurrent Digynic Triploidy.**

Signed ..... Date 20/10/'09...
David Archard (Chair)