HFEA Licence Committee Meeting
12 May 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

IVF Hammersmith (0078) – Application to add CGH as a PGS methodology

Members of the Committee:	
Emily Jackson, lay member – Chair Neva Haites, clinical geneticist Debbie Barber, nurse consultant Richard Harries, lay member	Committee Secretary: Kristen Veblen Legal Adviser: Sarah Ellson, 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:

- Papers for licence committee (39 pages)
- Tabled papers:
    1. "Oocyte karyotyping by comparative genomic hybridization provides a highly reliable method for selecting 'competent' embryos, markedly improving in vitro fertilization outcome: a multiphase study." *Fertility and Sterility* 20(10), 2007.
    2. "Successful pregnancies after application of array-comparative genomic hybridization in PGS-aneuploidy screening" *Reproductive BioMedicine Online*. 17(6), 2008.
    3. Email from Anastasia Mania to Sarah Hopper, 8 April 2009
    4. Email from Andrew Leonard to Steve Laverty 22 October 2008
    5. Licence Committee Minutes 13 Nov 2008, Item 7

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings

- 7th 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)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee considered the application form and PR's response, peer review and PR's response, patient information and consent forms, and the tabled papers.

2. The Committee discussed the scientific information provided to them and noted that metaphase CGH and array CGH were considered improvements on Fluorescent in Situ Hybridisation (FISH) technique, currently in use by the Centre. The Committee noted that metaphase CGH did not look at abnormalities in the sex chromosomes, while array CGH did.

3. The Committee also noted that the application was for both new techniques and that the tabled email from Anastasia Mania to Sarah Hopper addressed the issue raised by the peer reviewer as to how minor imbalances of unknown significance would be addressed, namely the technique would only be used to identify the number of chromosomes or significant changes in the chromosomes.

4. The Legal Advisor reminded the Committee of the guidance at G.5.8.1 as to the information to be given to patients considering PGS.

5. The Committee further noted that this Centre had their Licence Conditions amended on 13 November 2008 to reflect the anticipated amendments which will revise the Standard Licence Conditions from October 2009.

Committee's Decision

6. The Committee decided that it was within its remit to consider this application to authorise new tests for PGS to be conducted by the Centre. The Committee did not require further legal advice.

7. The Committee noted that it had received a signed application.

8. The Committee agreed to vary the Licence to recognise metaphase and array CGH as methods of PGS for those chromosomal aneuploidies for which the centre is licensed to conduct PGS.

9. The Committee recommended that the Centre develop two consent forms, one for each methodology, to ensure that patients were fully informed about the differences between metaphase and array CGH.

10. The Committee reminded the Centre that they were bound by their revised Licence Conditions, imposed following their acceptance of the invitation to vary their Licence Conditions extended by the Authority and communicated in an email from Andrew Leonard, dated 22 October 2008. The Committee in particular wished to remind the Centre of A.13.9(b)(ii) required that people seeking treatment be given written material about the experimental nature of this procedure, and in particular it specified that more robust randomised controlled trials were needed to assess whether or not PGS could significantly increase live birth rates for all indications. Also, A.13.9(e), which stated that centres should monitor the latest literature and professional guidance include a reference to the BFS policy and practice guidance on PGS; and A.13.9(f) which stated that centres should validate the use of PGS for each category of patients/indications they offered if for, based on data from previously published studies and retrospective evaluations of the Centre's own data. .

Signed..... Date 13.5.09.
Emily Jackson (Chair)