

HFEA Licence Committee Meeting

12 August 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 6

London Women’s Clinic (0105) – Variation to include PGS by fluorescence in situ hybridisation (FISH) and comparative genomic hybridisation (CGH) as a licensed activity

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) -- Chair	Kristen Veblen
Rebekah Dundas (lay) -- videolink	Legal Adviser:
Richard Harries (lay)	Stephen Hocking, Beachcroft LLP
Emily Jackson (lay)	
Apologies:	
William Ledger (clinician)	

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 (77 pages)
- no tabled papers.

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 21 January 2009.
1. The Committee considered the papers, which included an Executive Summary, application form, peer review, and various supporting documentation, including patient information and consent forms.
 2. The Committee noted that FISH-related and PGS techniques were well established and used extensively in other laboratories. Additionally, the Committee noted that the CGH technique was considered an improvement on the FISH technique.
 3. The Committee noted the peer review and observed that it was supportive of the application. Further, the Committee noted that the peer reviewer had found the patient information to be comprehensive, clear and containing sufficient references to counselling, and had judged the consent form to be satisfactory.
 4. The Committee reviewed the patient information provided, and while agreeing with the peer reviewer that the information was detailed and gave sufficient information, the Committee agreed that the information provided, while complete, initially emphasised the positive potential of these techniques, without placing sufficient up-front emphasis upon the equivocal evidence base for the use of these tests.
 5. The Committee wished to draw the attention of the Centre to the new Licence Condition T89(c)(i) and (ii), which would have effect from 1 October 2009:

With respect to any preimplantation genetic screening (PGS) programme the centre must ensure that:

(c) before the people seeking treatment give consent to preimplantation screening of embryos for aneuploidy they must be given an oral explanation supported by relevant written material:

(i) of the risks associated with the preimplantation screening for aneuploidy

(ii) of the unproven nature of the procedure, in particular that more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates for different specific indicators and it is likely that the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates.
 6. The Committee suggested that the Centre should amend its current patient information to be compliant with this Licence Condition, so as to avoid the need to rewrite it for compliance from 1 October 2009. This would

necessitate specifically including information about the risks and the unproven nature of these tests in the 'Background' section of the information sheet.

7. The Committee also wished to draw the Centre's attention to the British Fertility Society policy and practice guidelines on PGS: Anderson, R A and Pickering, S (2008). The current status of pre-implantation genetic screening: British Fertility Society Policy and Practice Guidelines. *Human Fertility* 11(2):71-75. Available at: www.britishfertilitysociety.org.uk/public/factsheets/PGS.html. The Committee agreed that the Centre's patient information would be more complete if a reference to these guidelines was included to enable patients to access further external information if they so desired.

The Committee's Decision

8. The Committee agreed that the proposed techniques were practices designed to secure that embryos were in a suitable condition to be placed in a woman and that they were desirable for the purpose of providing treatment services.
9. The Committee noted that it had received a signed application form.
10. The Committee decided to vary the licence to include pre-implantation genetic screening (PGS) by fluorescence in situ hybridisation (FISH) and comparative genetic hybridisation (CGH), as a licensed activity.

Signed Anna Carragher Date 25-8-2009
Anna Carragher (Chair)