

HFEA Licence Committee Meeting

22 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 9

The James Cook University Hospital (0055) – Change of Nominal Licensee and variation of the licence to include storage of eggs

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) – Chair	Kristen Veblen
Rebekah Dundas (lay) – by videolink	Legal Adviser:
Richard Harries (lay)	Mary Timms, Field Fisher Waterhouse
Apologies:	
Emily Jackson (lay)	
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 (18 pages)
- tabled papers – Application to vary licence and Executive Summary plus attachment (14 pages).

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.

Change of Nominal Licensee

1. The Committee considered the papers for the Change of Nominal Licensee, which included an executive summary and an application made by Mr Fayez Mustafa, the Person Responsible, for Mr Derek Cruickshank to be recognised as the new Nominal Licensee. The Committee noted that this application was signed, and included both the CV of the prospective Nominal Licensee and a signed resignation from the current Nominal Licensee.
2. The Committee considered Mr Cruickshank's CV and noted that he was a Consultant Gynaecologist at South Tees Hospitals NHS Foundation Trust. The Committee noted that he was appropriately qualified and had appropriate experience.
3. On the basis of the information before it, the Committee agreed that it was satisfied that Mr Cruickshank was a suitable person to hold the licence.

The Committee's Decision

4. The Committee decided to vary the licence, as requested, to recognise Mr Derek Cruickshank as the Nominal Licensee for the Centre.

Variation of Licence to Add Storage of Eggs

5. The Committee considered the papers, which included an executive summary, application, patient information and centre protocols.
6. The Committee noted that the Centre wished to store eggs in order to improve their service.
7. Considering the patient information sheet, the Committee observed that there was no reference to statistics for live birth rates from ICSI using frozen eggs and agreed that the patient information would be more complete if it were to include a sentence giving the range of live births, at the end of the second paragraph on page two.
8. Additionally, the Committee felt that the last sentence of the third paragraph of page two should include the word 'vary' after 'success rates', to make clear that there was a significant variation.

The Committee's Decision

9. The Committee noted that a signed application for the procedure had been received from the Centre. It also took into account the recommendation by the Executive that the application be granted.

10. The Committee noted that the Executive Summary stated that the Centre had appropriate premises and equipment for this procedure and suitably qualified and experienced staff.
11. The Committee agreed that with the above discussed modifications, the patient information sheet was suitable.
12. The Committee was satisfied from the information in the Inspector's report that the Centre had the correct facilities and procedures in place to provide storage of eggs in accordance with the stipulations of the HFE Act 1990 (as amended) and the Code of Practice.
13. The Committee decided to vary the Centre's licence to add storage of eggs.

Signed.....**Approved by the Chair**..... Date.....**5 August 2009**.....
Anna Carragher (Chair)