

# Licence Committee Meeting

26 April 2007

21 Bloomsbury Street London WC1B 3HF

## MINUTES Item 19

### James Cook University Hospital (0055)

### Licence Variation pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

#### Members:

Clare Brown, Lay Member – Chair  
Ruth Fasht, Lay Member  
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service  
Chris Barratt, Head of the Reproductive Biology and Genetics Research Group at the University of Birmingham  
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

#### In Attendance:

Frances Clift, Legal Adviser  
Marion Witton, Head of Inspection  
Claudia Lally, Committee Secretary

#### Observers:

Shirley Harrison, HFEA Chair

Conflicts 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 (3 pages)
- no papers were tabled.

1. The papers for this item were presented by Janet Kirkland, HFEA Inspector. Ms Kirkland drew the Committee's attention to the centre's risk rating with regard to compliance with the EUTCD, which was 13%, in the low range. She informed the Committee that this is a compliant centre

2. Ms Kirkland drew the Committee's attention to the particular areas of non-compliance, which were:

- Third party agreements
- Establishment and maintenance of a Quality Management System (including the requirement for a skeleton framework for a Quality Manual)
- Accreditation
- Monitoring and evaluation of processes.

3. The Committee noted that the report states that there is no evidence in the centre's application that the diagnostic laboratories they use are accredited. The Committee asked Ms Kirkland to follow up this point and Ms Kirkland returned to the meeting with evidence that the laboratory is accredited by the CPA.

4. The Committee noted that the centre is working towards full compliance with the requirements of the EUTCD and that progress will be assessed at the next inspection visit to the centre.

5. The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Signed..... Date.....  
Clare Brown (Chair)