

Licence Committee Meeting

7 June 2007

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Leicester Fertility Centre (0068) Licence Renewal

Members of the Committee:

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

In Attendance:

Trish Davies, Director of Regulation / Deputy Chief Executive
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Providing Legal Advice:
Eve Piffaretti, Morgan Cole Solicitors

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 (47 pages)
- no papers were tabled.

1. The papers for this item were presented by Tony Knox, HFEA Inspector. Mr Knox informed the Committee that this centre has been licensed since 1992 and treats a mixture of NHS and privately funded patients. It has a good history of regulatory compliance. Mr Knox also advised the Committee that the centre has acquired a new Person Responsible since the last inspection which has raised the centre's risk score to 21%, in the medium range.

2. Mr Knox advised the Committee that two breaches were noted during the renewal inspection of the centre: witnessing of samples being removed from a dewar was not being carried out in accordance with witnessing directions D2004/4 and a sample was identified that was being stored beyond the expiry of the storage consent. He further informed the Committee that measures were put in place by the centre on the day of the inspection to address these breaches.

3. Mr Knox further informed the centre that a number of recommendations were made by the inspection team in the course of the inspection. These included the recommendation to ensure that emergency equipment is

regularly checked (and records kept whenever checks take place) and the recommendation that the centre ensures that the cryostore door is kept closed when not in use. Mr Knox reported that these recommendations have all now been implemented.

4. The Committee noted the breaches reported by Mr Knox and agreed to renew the centre's licence for a period of three years with no additional conditions. The decision to renew the centre's licence for three years rather than for five was made on the basis of the centre's medium risk score.

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