

Licence Committee Meeting

5 June 2008

21 Bloomsbury Street London WC1B 3HF

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HFEA REGULATION

MINUTES Item 7

Assisted Conception Unit Leigh Infirmary, 0278 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
Roger Neuberg, Consultant
Obstetrician and Gynaecologist,
Leicester Royal Infirmary

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:

Sarah Ellson, Field Fisher Waterhouse
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 (30 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre is located on the first floor of the Women's Unit at Leigh Infirmary. The unit provides day case surgical treatment, induction of ovulation and intrauterine insemination (IUI). The centre appears to be well managed and is making good efforts in ensuring compliance with EUTD requirements.

2. Mrs Walsh summarised the areas for improvement detailed at pages 6 and 7 of the inspection report. These included:

- the requirement to finalise third party agreements
- the requirement to improve the Quality Management system (QMS)
- the requirement to establish documented procedures for the home procurement of sperm
- the requirement to plan validation of equipment and processes
- the requirement to document assessments of staff competencies
- the requirement for a documented procedure for adverse incidents

- the requirement to revise witnessing protocols.

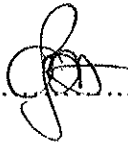
3. Mrs Walsh informed the Committee that the centre is making good progress with respect to the recommendations in the inspection report, most of which have now been actioned. The centre has now started to formally document staff competencies, for example, and has revised witnessing protocols. Accordingly she recommended that the licence is renewed for a period of 4 years.

The Committee's Decision

4. The Committee agreed that it was satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

5. The Committee decided to renew the centre's licence for a period of 4 years with no additional conditions. The Committee noted that the centre had only recently been invoiced for the licence fee which consequently had not yet been paid. The Committee remind the centre that a new licence cannot be issued until such time as the licence fee has been received.

Signed.....
Clare Brown (Chair)



Date.....

11/6/08