

Research Licence Committee Meeting

25 July 2007

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

Research Project R0169: Analysis of chromosomes in human preimplantation embryos using FISH and CGH Based at London Fertility Centre (0088) Licence Renewal

Members:

Richard Harries – Chair, Lay Member
Clare Brown, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary
William Ledger – Professor of Obstetrics and Gynaecology, University of Sheffield
Rebekah Dundas – Lay Member

In Attendance:

Marion Witton – Head of Inspection
Frances Clift, Legal Adviser
Joanne McAlpine, Acting Committee Secretary
Barbara Lewis, Observer

Conflicts of Interest: members of the committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (50 pages)
- no papers were tabled.

1. The papers for this item were presented by Ms Sarah Hopper. Ms Hopper informed the Committee that the project has been licensed since January 2006 and the licence is due to expire in December 2007. She drew the Committee's attention to the fact that the peer reviewer supported the renewal of the licence for a further 12 months.

2. Ms Hopper confirmed that embryos used in the research project are donated by Centre 0068 Leicester Fertility Centre and by patients attending for treatment at centre 0088. 86 embryos have been used in the project so far.

3. Ms Hopper informed the committee that during the inspection visit on 7 June 2007, it was noted that on six occasions embryos donated to the project had

been stored beyond their statutory storage period. Also, when the embryo records were checked, there was one occasion when a consent form was in place for the female partner only, not for both gamete providers.

4. Ms Hopper confirmed that the PR has amended the protocols in relation to patient consent and scientific practice as recommended by the inspection team.

5. The Committee noted the issues for consideration summarised at pages 8 and 9 of the inspection report. The Committee shared the concerns of the inspection team but were satisfied that as a result of recommendations made at the inspection visit, appropriate steps are being taken by the centre to address these concerns.

6. The Committee applied the statutory tests in considering the application. To start, the Committee identified the activity under consideration as the use of embryos for research.

7. The Committee agreed that this activity appears to be necessary or desirable for the following specified purposes:

- Increasing knowledge about the causes of miscarriages
Human Fertilisation and Embryology Act 1990 Schedule 2 3(2)(c)
- Developing methods for detecting the presence of gene or chromosome Abnormalities in embryos before implantation
Human Fertilisation and Embryology Act 1990 Schedule 2 3(2)(e)
- Increasing knowledge about the development of embryos
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 S 2(a)

8. The Committee agreed that they were satisfied that the proposed research could not be undertaken without the use of human embryos.

9. The Committee agreed that they were satisfied with the patient information and consent forms submitted by the centre, however suggested that in the information sheet it states that the patient can withdraw consent at any time, but has no explanation as to how this can be done.

10. The Committee were satisfied that the requirements for granting a licence under section 16 of the Human Fertilisation and Embryology Act 1990 were fulfilled and decided to renew the licence for research for a period of one year after taking into account the breaches which had been identified.

Signed..... Date.....
Richard Harries (Chair)