

# Research Licence Committee Meeting

26 July 2006

21 Bloomsbury Street London WC1B 3HF

## MINUTES Item 7

**Research Project: R0075 Improving Methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality, based at Assisted Conception Unit, Guy's and St Thomas' hospital NHS Trust (0102)**

### **Licence Renewal**

**Also, progress reports were presented on research project R 0133**

#### Members:

Emily Jackson, Lay Member – Chair  
Ivor Brecker, Lay Member  
Richard Harries, Lay Member  
Clare Brown, Lay Member  
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

#### In Attendance:

Chris O'Toole, Head of Research Regulation  
Claudia Lally, Secretary to the Committee

#### Providing Legal Advice:

Graham Miles, Morgan Cole Solicitors

#### Providing Scientific Advice:

Neva Haites, Professor of Medical Genetics, University of Aberdeen

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 (134 pages)
- no papers were tabled.

1. The papers for this item were presented by Chris O'Toole, Head of Research Regulation. Dr O'Toole informed the Committee that the peer review of the project had been favourable. However, a potential breach of the Human Fertilisation and Embryology Act 1990 had been reported by the inspection team, namely the use in the research project of an embryo from patients who had indicated that they did not consent to the use of their embryos in research. The Committee noted that the patients might have provided consent in an additional consent form but that no such form was included in the patient notes.

2. The Committee noted this serious breach of the Act and requested that the Executive record this breach in the centre's licensing history. The Committee agreed that the centre must take steps to ensure that this never happens again. The Committee asked that the centre indicate to the Executive the additional training and safeguards it intends to put in place to ensure that it cannot happen again, and also indicate a timescale by which these will be completed. The Committee further requested the Executive makes this issue a focus for the next inspection.
3. The Committee noted what the inspection team identified as a slight blurring of roles between the research personnel and staff involved in the treatment of patients. The Committee agreed to remind the centre that where patients are to be approached about the possibility that they might enter an egg sharing arrangement in which a proportion of their eggs would be donated for use in research those patients must not receive information, consenting and / or counselling concerning the research from clinical personnel involved in the project of research.
4. The Committee noted that the list of research purposes for the licence had not been captured on the faxed peer review form, and asked the Executive for clarification on these points with the peer reviewer.
5. The Committee noted the progress report for research project R0133.
6. The Committee noted that the centre had applied to change the Person Responsible for the project of research. On the basis of the information contained in the committee papers, the Committee agreed that Professor Peter Braude and Mr Yacoub Khalaf are suitable people to be the Person Responsible and Nominal Licensee respectively and agreed that this change would be recorded in the licenses for project R0075 and R0133.
7. The Committee agreed to apply the statutory tests in considering the renewal application for project R0075. The Committee identified the activity to be authorised by the licence as the removal of blastomeres from embryos and the fixing of embryos.
8. Members agreed that this activity is not prohibited under the Human Fertilisation and Embryology Act 1990 (the Act).
9. Members agreed that the activity is necessary or desirable for the following purposes:
  - developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation  
*Human Fertilisation and Embryology Act 1990 Schedule 2 s3(2)(e)*

- increasing knowledge about serious disease  
*Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(b)*

10. The Committee agreed that they were satisfied that the use of embryos is necessary for the purpose of the research.

11. The Committee agreed that they were satisfied with the consent forms and patient information provided by the centre.

12. The Committee were satisfied that the requirements for the grant of a licence under Section 16 of the Human Fertilisation and Embryology Act 1990 are satisfied, and decided to grant a licence for the research for a period of three years.

Signed..... Date.....  
Emily Jackson (Chair)