

Research Licence Committee Meeting

2 April 2008

21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Research Project R0133: Correlation of embryo morphology with ability to generate embryonic stem cell lines and subsequent growth and differentiative characteristics

Licence renewal

Guy's Hospital (0102)

Research Project R0075: Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality

Progress report

Guy's Hospital (0102)

Members:

Emily Jackson – Chair, Lay Member
Richard Harries, Lay Member
Clare Brown, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary
Neva Haites, Professor of Medical Genetics, University of Aberdeen

In Attendance:

Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary
Joanne McAlpine, Inspections, Logistics and Reporting Officer
(present via conference telephone:)
Vicki Lamb, HFEA Inspector

Providing Legal Advice:

Mary Timms, Field Fisher Waterhouse

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 (82 pages)
- no papers were tabled.

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that the issue of consents had been a key focus of this inspection, following the finding of the previous inspection that an embryo had been used in research for which no consent for this use could be found. This inspection found that a robust system has been put in place for ensuring that effective consent is in place for all material used in the project. Dr Lamb affirmed

that no discrepancies were found in the audit of patient records during the inspection.

2. Dr Lamb informed the Committee that the centre would like to make small changes to the lay summaries for both projects. These changes are supported by the Executive. She drew the Committee's attention to the fact that the inspection team has recommended that new standard operating procedures be developed for the induction of new members of staff. Dr Lamb also informed the Committee that the two projects appear to be progressing well and that the peer review contained in the committee papers at pages 75-79 is very positive about the renewal of project R0133.

3. Dr Lamb informed the Committee that the Person Responsible has satisfactorily completed the Person Responsible Entry Programme assessment.

The Committee's Decision in relation to the application to renewal the licence for research project R0133

4. The Committee endorsed the recommendation in relation to the creation of an SOP for the induction of new staff and asked that this be completed, and submitted to the Executive, by Monday 12 May. The Committee also approved the centre's request to slightly alter the lay summary of the project.

5. The Committee identified the activities to be authorised by a licence as the use of embryos in research, the storage of embryos and the derivation of human embryonic stem cell lines. The Committee agreed that they were satisfied that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990.

6. The Committee decided that these activities are necessary and desirable for the following purposes:

- Increasing Knowledge about the development of embryos
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(2)(a)
- Increasing Knowledge about serious disease
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(2)(b)
- Enabling any such knowledge to be applied in developing treatments for serious disease
Human Fertilisation and Embryology (Research Purposes) Regulations 2001 s2(2)(c)

7. The Committee decided that it was satisfied that the proposed use of embryos is necessary for the purpose of research, since the use of embryos is fundamental to this project, with its focus on the generation of embryonic stem cell lines.

8. The Committee noted that no issues for consideration were raised in the inspection report in relation to patient information or consent forms. However, the Committee recognised that these will need to be changed to reflect the changes in the lay summary.

9. The Committee noted that the Person Responsible has completed the Person Responsible Entry Programme assessment and took into account the evidence in the inspection report as to the suitability of the premises. The Committee decided that the requirements for granting (and therefore renewing) a licence under section 16(2) of the Human Fertilisation and Embryology Act 1990 are satisfied.

10. The Committee noted that the centre had not yet paid its licence fee. The Committee agreed to renew the licence for a period of three years subject to the payment of this fee.

The Committee's Decision in relation to the progress report for research project R0075

11. The Committee endorsed the recommendation in relation to the creation of an SOP for the induction of new staff and asked that this be completed, and submitted to the Executive by Monday 12 May. The Committee also approved the centre's request to slightly alter the lay summary of the project.

12. The Committee agreed that they were content for this licence to continue with no additional conditions.

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