

Research Licence Committee Meeting

9 May 2007

New Century House Corporation Street Manchester

MINUTES Item 2

Project R0136: Platform technologies underpinning human embryo stem cell derivation

Based at the Roslin Institute (0202)

Licence Renewal

Members of the Committee:

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

In Attendance:

Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Observing

Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service

Providing Scientific Advice:

Neva Haites, Professor of Medical Genetics, University of Aberdeen

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 (157 pages)
- no papers were tabled.

1. The papers for this item were presented by Sarah Hopper, HFEA Inspector. Ms Hopper informed the Committee that the licence for this project expires in June 2007. The project receives embryos donated from three separate research centres which arrive at the blastocyst stage of development. To date the project has generated 7 stem cell lines, 6 of which have been deposited in the National UK Stem Cell Bank. Ms Hopper drew the Committee's attention to the comments of the peer reviewer, who recommended that the application to renew the research licence be accepted in its current form.

2. Ms Hopper drew the Committee's attention to the areas requiring attention as listed in the inspection report. These were that the centre formalises its incident handling policy and that staff training is formally logged.
3. Ms Hopper informed the Committee that the previous NL will be leaving and that an application had been received for Mr Malcolm Bateman to take up this role.
4. The Committee discussed the patient information and consent forms being used by patients who donate material to the project. Lay members of the Committee suggested a few minor amendments to these documents with a view to enhancing their clarity and sensitivity. Ms Hopper was asked to discuss these amendments directly with the PR of the project. In general, the recommendations applied the following principles:
 - a) Patient information makes it clear to IVF patients that they may wish to consider donating embryos which will not be used in any ongoing treatment. These embryos may be unsuitable for freezing, but care should be given to how the patient information refers to them. In particular, embryos should not be identified as merely "unsuitable" nor as "not needed", since some patients may still 'need' their embryos but be unable to afford further treatment
 - b) Patient information should clearly state that patients can withdraw their consent to the use of material in research at any point "until the eggs have been transferred to the research project". Attempts to define this point differently (particularly using clinical terms) may not be easy for donors to understand.
 - c) All patient information should not only remind patients about this possibility of withdrawing consent but should provide a contact name and contact details should they wish to do so.
5. The Committee agreed that the lay summary of work undertaken which had been received was insufficiently lay-friendly and asked that this be re-written and re-submitted for publication on the Authority's website.
6. The Committee applied the statutory tests in considering the application. To start, the Committee identified the activities under consideration as the derivation of embryonic stem cell lines, the creation of embryos and the use of donated embryos in research. The Committee agreed that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990.
7. The Committee agreed that in the context of the project of research these activities appear to be necessary or desirable for the following specified purposes:
 - Human Fertilisation and Embryology Act 1990 Schedule 2 3(2)(a) Promoting advances in the treatment of infertility.

- Human Fertilisation and Embryology Act 1990 Schedule 2
3(2)(b) Increasing knowledge about the causes of congenital disease
- Human Fertilisation and Embryology Act 1990 Schedule 2
3(2)(c) Increasing knowledge about the causes of miscarriages
- Human Fertilisation and Embryology (Research Purposes) Regulations
2001:
2(2)(b) Increasing knowledge about serious disease.
- Human Fertilisation and Embryology (Research Purposes) Regulations
2001:
2(2)(c) Enabling any such knowledge to be applied in developing
treatments for serious disease.

8. The Committee agreed that they continued to be 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 subject to the points made in paragraph 4 (above).

10. 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. In addition, the Committee approved Mr Malcolm Bateman as the new Nominal Licensee for the project.

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