

# Research Licence Committee Meeting

28 March 2007

21 Bloomsbury Street London WC1B 3HF

## MINUTES Item 1

**Comparative studies on human embryonic stem cells and stem cells derived from male germ cells (R0174)**  
**Based at the Institute of Reproductive and Developmental Biology, Imperial College London (0249)**  
**Licence Renewal**

### Members:

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  
Claudia Lally, Committee Secretary

### Observing:

Diane Malcolm, PA to HFEA Chair

### Observing:

Shirley Harrison, HFEA Chair  
Roger Neuberger, Consultant Obstetrician and Gynaecologist

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 (45 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 this project received its initial licence last year. It is based at Imperial College and is closely affiliated with Hammersmith Hospital IVF Clinic where the embryos used in the project are sourced. The project aims to compare the development of human embryonic stem cells and adult germ cells derived from adult testes. During the previous year some progress had been made with the project but not as much as had

been hoped. This was partly to do with the consent form being used at Hammersmith Hospital which did not ask for consent for embryos to be used in the production of stem cell lines. The consent forms have now been amended accordingly and it is expected that progress with the project will pick up.

2. Dr O'Toole reminded the Committee that one of the reservations the Committee had expressed when licensing the project was that the Person Responsible for the project was to be based in California and would therefore not necessarily be in a good position to implement effective governance arrangements. Dr O'Toole reported that the Person Responsible had actually been present at the centre far more frequently than had been planned and the research team had expressed their view that the arrangements were working well. Dr Poon was in day to day charge of the work when the Person Responsible was absent. Dr O'Toole suggested to the Committee that they might want to consider requiring the Person Responsible to undertake training in the form of the Person Responsible Entry Programme (PREP).

3. The Committee noted that the location of the Person Responsible did not appear to be having a detrimental effect on the research project and agreed with the suggestion that the Person Responsible should undertake the Entry Programme, particularly in light of the fact that its use is now standard, with Persons Responsible for Treatment and Storage Licences all being required to submit a completed assessment by the end of April this year. The Committee further noted that the Person Responsible for the project had already expressed her willingness to undertake the training. They decided that the Person Responsible should be requested to complete the PREP within three months of receipt of these minutes.

4. The Committee noted that page 9 of the inspection report recommends that the patient information for patients considering donating testicular tissue to the research does not inform patients that they can withdraw consent from the project and how they can do so. The Committee endorsed this recommendation.

5. The Committee agreed to apply the statutory tests in considering the application. To start, the Committee identified the activities under consideration as the derivation of embryonic stem cell lines 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.

6. 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 (Research Purposes) Regulations 2001:  
2(2)(a) Increasing knowledge about the development of embryos.

- 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.

7. The Committee agreed that they continued to be satisfied that the proposed research could not be undertaken without the use of human embryos.

8. 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).

9. 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)