

## **Research Licence Committee Meeting**

**18 June 2008**

**21 Bloomsbury Street London WC1B 3HF**

### **MINUTES Item 9**

**Research Project R0152: Derivation of human embryonic stem cell lines using nuclear transfer and parthenogenetically activated oocytes  
Based at Newcastle Fertility centre at Life (0017)  
Licence Renewal**

**Members:**

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

**In Attendance:**

Trish Davies, Director of Regulation/  
Deputy Chief Executive  
Chris O'Toole, Head of Research Regulation  
Claudia Lally, Committee Secretary

**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 tabled papers were considered by the Committee:

- papers for the Committee (52 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 aims to derive human embryonic stem cells using nuclear transfer and parthenogenic activation. Dr O'Toole further informed the Committee that progress with this project has been hampered by a refurbishment of the laboratories and by the availability of good quality of eggs. During 2007 the research project used 19 fresh eggs and 56 failed to fertilise eggs. The centre has recently received a grant from the MRC to approach women about egg sharing for research and it is hoped that the research will now progress at a faster pace. Dr O'Toole informed the Committee that the Person Responsible for the research has satisfactorily completed the Person Responsible Entry Programme (PREP) assessment, that the Nominal Licensee, Mary Herbert, is a suitable person to hold a licence, and that the licence renewal fee has been paid.

## The Committee's Decision

2. The Committee noted and endorsed the recommendation in the inspection report that the centre needs to implement a formal, written standard operating practice for the periodic review of stored donated material and in addition should keep a record of patients who have been sent background information or who have discussed the research with the research coordinator or research nurse.

3. The Committee identified the activities under consideration as the storage of embryos, the use of donated embryos in research, the creation of embryos in vitro and the derivation of human embryo stem cell lines. The Committee agreed that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990.

4. The Committee considered whether the proposed activities appear either necessary or desirable for one or more of the purposes as set out in paragraph 3(2) of Schedule 2 to the 1990 Act or in paragraph 2(2) of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. The Committee considered the stated aims of the project and the evaluation of the project by the peer reviewer and agreed that in the context of the project of research these activities appear to be necessary or desirable for the following purposes:

- Human Fertilisation and Embryology (Research Purposes) Regulations 2001:  
2(2)(a) to increase knowledge about the development of embryos.
- Human Fertilisation and Embryology (Research Purposes) Regulations 2001:  
2(2)(c) to enable any such knowledge to be applied in developing treatments for serious disease

In reaching this decision the Committee took into account the comment by the peer reviewer that the work aims to create patient specific stem cells for potential future treatments for disease.

5. The Committee agreed that this use and creation of embryos is necessary for the purpose of the research. In making this decision, the Committee took into account the comment by the peer reviewer that induced pluripotent (iPS) cells could not be used in place of stem cells since iPS cells are derived by viral insertion and the use of such cells is presently not considered compatible with clinical application.

6. The Committee agreed that they were satisfied about the consent forms and patient information, based on the remarks of the Executive.

7. The Committee noted Dr O'Toole's comments today and in her report about the suitability of the Person Responsible, the Nominal Licensee and the premises, and agreed that the requirements for the grant of a licence under Section 16 of the Human Fertilisation and Embryology Act 1990 were satisfied. The Committee decided to renew the licence for a period of three years. The Committee considered that 3 years was an appropriate period given that this is a well-established Centre.

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