

Licence Committee Meeting

12th January 2005
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

Centre: Division of Gene Expression and Development, Roslin Institute (0202)

Initial Application for research project: Derivation of human embryo stem cell lines by cell nuclear replacement for technology development and the study of Motor Neurone Disease

Members of the Committee:

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

Apologies from:

Neva Haites
David Barlow
Sara Nathan

In Attendance:

Hossam Ibrahim Abdalla, (Director, Lister Fertility Clinic) in his capacity of Clinical Adviser
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Ross Thacker, Research Officer
Claudia Lally, Secretary to the Committee

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 (108 pages)
- 1 paper was tabled: this comprised a response to the peer review from the applicant, and a further response from the peer reviewer. This tabled paper comprised 4 pages.

1. The papers were presented by Chris O'Toole, Head of Research Regulation. Dr O'Toole summarised the proposed research project as set out in the papers.

2. The Committee agreed that they were satisfied that the two peer reviewers' reports provided them with sufficient expert advice to make a decision.

3. The Committee identified the activities to be authorised by the licence as:

- (a) the creation of embryos through the use of CNR and parthenogenesis
- (b) the development of blastocysts from those embryos
- (c) the isolation of stem cells from those blastocysts.

4. The Committee agreed that none of these activities are prohibited under the Human Fertilisation and Embryology Act 1990.

5. The Committee noted the views of the peer reviewers, who both agreed that the proposed research was necessary or desirable for the following purposes:

- Increasing knowledge about the causes of congenital disease
- Increasing knowledge about serious disease
- Enabling any such knowledge to be applied in developing treatments for serious disease.

These purposes are set out in Schedule 2.3 (2)(b) to the Human Fertilisation and Embryology Act 1990, and in the Human Fertilisation and Embryology Act (Research Purposes) Regulations 2001, section 2(2)(b) and section 2(2)(c). The Committee agreed with the peer reviewers that the proposed research project fulfilled these purposes when considered as a whole, for the reason that the research aims to create different types of cell lines with a genetic pre-disposition to Motor Neuron Disease (which is a serious congenital disease) and, using these cell lines, to study the genetic nature of the disease and how this genetic nature expresses itself in the development of the physiological manifestations of the disease. The research also aims to use these cell lines in testing how drug treatments affect different types of cells with a genetic disposition to the disease.

6. The Committee further decided that each component activity (a - c) fulfils the three above purposes, for the reason that each is necessary for the project as a whole.

7. Members noted the comment by one of the peer reviewers (see page 88 of the papers) that “the proposed utilisation of human embryos is necessary as other approaches to develop models of this kind have not been developed and applied to MND.” The same peer reviewer also asserts that experiments on animal models or other types of human cells have reached a point at which the use of human embryos is justified. The Committee agreed that they were satisfied that the creation of embryos by CNR and parthenogenesis is necessary for the purposes of the research in order to create cell lines of a known genetic composition, specifically a genetic pre-disposition to Motor Neuron Disease. The Committee considered the number of oocytes that the researchers have predicted that they will use during the course of this project. They agreed that given the novelty of this research and the expected success rates the proposed use of this number of embryos was necessary.

8. The Committee considered the patient information and consent forms, and agreed that consent given by patients complies with the standard licence conditions on all licences for treatments involving the use of embryos to derive

stem cells. However, Members also agreed that there were two aspects of the consent forms with which they were not happy. The first aspect was a sentence at the end of the consent form which reads: "thank you for agreeing to take part in this important research". In line with previous Licence Committee decisions, the Committee agreed that the word "important" should be removed from this sentence, so that patients do not feel under any pressure to participate. The second aspect was the question in the consent forms which asked the consenting patient whether they wish to received feedback on research results which have implications for their health. The Committee agreed that because the results of this research would not have any meaningful implications for the health of particular patients, this option must be removed from the consent forms.

9. The Committee considered whether the requirements for the grant of a licence as set out in Section 16 of the Human Fertilisation and Embryology Act 1990 have been satisfied. They concluded that they were satisfied:

- that the application fee has been paid
- that the Nominal Licensee is a suitable person to hold a licence
- that the character, qualifications and experience of the proposed Person Responsible are such as are requires for the supervision of the proposed activities, and that he will discharge his duty under Section 17 under the Human Fertilisation and Embryology Act 1990
- that the premises in respect of which the licence is to be granted are suitable for the proposed activities.

10. The Committee therefore decided to grant a licence for the proposed research project with no additional conditions, subject to the centre making the two small changes to the consent forms as detailed in (5) above to the satisfaction of the Executive. The Committee agreed that this licence should be a 12 month licence, and that the centre should be required to submit a progress report to the HFEA every six months for the duration of the licence.

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