

**Research Licence Committee Meeting**  
**15 September 2004**  
**21 Bloomsbury Street London WC1B 3HF**

**MINUTES**

**Centre: 0017 Newcastle Fertility Centre at Life**  
**Application for Research Licence (AP-04-153)**

Members:

Sara Nathan –Chair  
Emily Jackson  
Neva Haites  
Ivor Brecker  
Maybeth Jamieson

Also present:

Claudia Lally, secretary to the Committee  
Trish Davies, Director of Regulation  
Frances Clift, Legal Adviser  
Ross Thacker, Regulatory Officer

Present in the capacity of clinical  
adviser:  
David Barlow

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 (86 pages)
- no papers were tabled

The papers were presented to the committee by Chris O'Toole, Head of Research Regulation. Dr O'Toole summarised the research project, explaining that the project entailed removing the pronuclei from one zygote (a one cell embryo) and transferring it to an enucleated zygote. Dr O'Toole communicated what she felt to be a question about the legality about this procedure in respect of two parts of the Human Fertilisation and Embryology Act 1990 (the Act):

- Section 3 (3)d, which prohibits “replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.”
- Section 3(4) of Schedule 2 to the Act, which provides that “a licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in circumstances (if any) as may be specified in or determined in pursuance of regulations.”

The Committee firstly considered paragraph 3(3)d of the Act. They agreed that this proposed project would not be prohibited under this section as a pronucleus is not the same as a nucleus. Following agreement on this distinction between a nucleus and a pronucleus, a prohibition on replacing a cell nucleus would not extend to cover the replacement of the pronuclei.

The Committee then considered paragraph 3(4) of Schedule 2 to the Act, which prohibits altering the genetic material of any cell while it forms part of an embryo. Members were in agreement that pronuclear transfer to an enucleated zygote does constitute the alteration of the genetic structure of an embryo. Furthermore, members noted that this alteration takes place from which ever perspective one views the pronuclear transfer. That is, the enucleated zygote acquires new genetic material in terms of the DNA contained in the pronuclei it receives, and the pronuclei also acquire new genetic material in terms of the mitochondrial DNA within the enucleated cell in which they are introduced.

Legal advice given:

The Committee noted the legal advice provided by Morgan Cole, Solicitors (in a statement dated 6<sup>th</sup> September 2004, presented in pages 8-15 of the papers for Licence Committee) and the advice of the in-house legal adviser that the activities of the proposed research were not prohibited under paragraph 3(3)(d) of the Act but were prohibited by the provisions of Schedule 2(3)(4).

The Committee decided:

1. Not to licence the proposed research.
2. That a letter be sent to the Person Responsible advising her that though the Committee found the proposal interesting, the Authority is prohibited from granting a licence as paragraph 3 (4) of Schedule 2 to the Human Fertilisation and Embryology Act provides that “a licence cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations.”

Signed..... Date.....  
Sara Nathan (Chair)