

**Minutes of Licence Committee of 3 August 2004 at 21 Bloomsbury Street  
at 11.00 a.m.**

Present

Members

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Executive

[REDACTED]  
[REDACTED]  
[REDACTED]

**Centre:** Newcastle Fertility Centre at LIFE

**Centre No:** 0017

**Person Responsible:** Professor Alison Murdoch

**Initial Application for a Research Licence: Derivation of human  
embryonic stem cell lines using Nuclear transfer and Parthenogenetically  
Activated Oocytes**

1. Apologies were received from [REDACTED].
2. [REDACTED] was present throughout the meeting of the Licence Committee to provide clinical advice.
3. [REDACTED] declared that the Centre at which he works also holds a research licence involving the derivation of human embryonic stem (hES) cells.
4. [REDACTED] presented the Centre's application for a research licence to create embryos by cell nuclear replacement and by parthenogenetically activating oocytes. These embryos will then be used to derive embryonic stem cell lines.
5. The Committee noted that the Centre's original application proposed to create embryos using adult nuclei from three sources:
  - Stem cell lines – nuclei from cells from the Centre's existing derived ES cell line (activity 1)
  - Women undergoing a gynaecological procedure – a skin biopsy will be taken from a woman undergoing a routine gynaecological operation (activity 2)
  - A patient with Type 1 diabetes – a skin biopsy will be taken from one patient who has Type 1 diabetes (activity 3)

6. The Committee noted that it had considered the original application at its meeting on 16 June 2004 and that it had been satisfied that the first two activities i.e. to derive human embryonic stem (hES) cell lines from human embryos created by the transfer of nuclei taken from (1) the Centre's existing stem cell line and (2) skin biopsies taken from women undergoing gynaecological procedures into enucleated oocytes, were necessary or desirable for "*increasing knowledge about the development of embryos*" and, in the case of the second activity, for "*enabling any such knowledge to be applied in developing treatments for serious disease*" [in accordance with the purposes set out in paragraph 3(2) of Schedule 2 to the HF&E Act 1990 (as amended by the HF&E (Research Purposes) Regulations 2001)]. The Committee had also agreed that the creation of embryos by CNR was necessary for the purpose of research. However, in reference to the third activity to derive human embryonic stem (hES) cell lines from human embryos created by the transfer of nuclei taken from skin biopsy from a patient who has Type 1 diabetes, the Committee noted that it had not, at the time, had the evidence to satisfy itself that this activity was necessary or desirable for the purposes set out in the HF&E Act 1990 (as amended). Therefore the Committee noted that it had agreed that it would adjourn and reconsider the application for this activity upon receipt of independent expert opinion on the genetics of diabetes and whether the use of hES cell lines derived from embryos created by CNR using the nuclei taken from a cell of a patient with Type 1 diabetes would be necessary or desirable for increasing the knowledge about this serious disease or enabling any such knowledge to be applied in developing treatments for this serious disease.

7. The Committee also noted that, at its meeting on 16 June 2004, it had agreed that prior to a research licence being granted for any of the activities in 5 above the following issues needed to be addressed:

- The patient information and consent forms. These needed to be revised taking into account the recommendations of the Research Licence Committee
- The role of the Person Responsible. It was considered that it would be difficult for one person to carry out the duties of Person Responsible in relation to both research and treatment. Therefore it had been proposed that the Centre should be given the opportunity to submit a revised application nominating a different individual as the Person Responsible for either this research project or the Centre's treatment licence.

8. [REDACTED] informed the Committee that the Person Responsible has asked that the application for a research licence to create embryos using nuclei of a skin cell taken from a patient with Type 1 diabetes (activity 3) be withdrawn. Therefore, the Committee noted that it was now considering the Centre's application to create embryos using adult nuclei from two sources:

- Stem cell lines – nuclei from cells from the Centre's existing derived ES cell line (activity 1)



- Women undergoing a gynaecological procedure – a skin biopsy will be taken from a woman undergoing a routine gynaecological operation (activity 2)
9. The Committee also noted that the Centre had submitted revised Patient Information and Consent Forms and that it was satisfied that these documents had addressed their concerns and now met their requirements.
  10. The Committee also noted that the Centre had proposed that Professor Murdoch remain the Person Responsible for the research project but that a different person, namely Dr Jane Stewart, takes on the duties of the Person Responsible for the Centre's treatment licence. It was noted that due to both the Nominal Licensee and Dr Stewart being away on holiday the Centre was unable to submit the necessary paperwork required to vary the Centre's treatment licence to change the PR. However, ██████████ reviewed Dr Stewart's qualifications and informed the Committee that Dr Stewart was appointed as a Consultant Gynaecologist in 2002 and that she is also a sub-specialist in Reproductive Medicine. Therefore, the Committee was satisfied that Dr Stewart was suitably qualified to fulfil the duties of the Person Responsible.
  11. The Committee noted that Professor Murdoch, in her letter dated 19 July 2004, had asked whether due to issues of conflict of interest raised in correspondence from pressure groups and / or interested parties she should withdraw as an Inspector for the HFEA. The Committee was reminded that, when approaching an inspector to inspect another licensed centre, the Executive asks both the inspector and the centre to declare any conflicts of interest. Therefore, the Committee agreed that it would not be necessary for Professor Murdoch to withdraw as an Inspector for the HFEA.
  12. The Committee noted the letters in support of this application, submitted by Professor Murdoch.
  13. The Committee also noted the correspondence from interested parties / pressure groups submitted since 16 June 2004. These documents had, in accordance with HFEA policy, been placed into the following categories:
    1. Relevant evidence based scientific and / or ethical opinion (addresses statutory criteria by analysis of scientific and / or ethical issues)
    2. Incomplete scientific and / or ethical opinion that nevertheless contains some evidence relevant to the statutory criteria
    3. Questions relating to HFEA licensing process
    4. Non evidence based statement of opinion
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14. The Committee confirmed the decision made at its meeting on 16 June 2004 having considered the additional material (referred to in paragraphs 12 and 13 above) that it was satisfied that the activities of the project i.e. to derive human embryonic stem (hES) cell lines from human embryos created by the transfer of nuclei taken from (1) the Centre's existing stem cell line and (2) skin biopsies taken from women undergoing gynaecological procedures into enucleated oocytes, are necessary or desirable for *"increasing knowledge about the development of embryos"* and, in the case of the second activity, for *"enabling any such knowledge to be applied in developing treatments for serious disease"*. The Committee had also agreed that the creation of embryos by CNR was necessary for the purpose of research.
15. The Research Licence Committee determined that once written consent of the new Person Responsible had been received by the HFEA in respect of the Treatment Licence for Centre 0017 it will grant a licence for a period of 12 months with the standard licence conditions for projects involving the derivation of embryonic stem cell lines.
16. The Committee also agreed to vary the Centre's licence R0145 so that embryos created through CNR could be used to be used for the derivation of human embryonic stem cell lines and epigenetic studies.

Signed: .....

(Chair)

Date: .....

August 9th 2004