Research Licence Committee Meeting

2 April 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 6

Research Project R0141: Evaluation of Cardiomyocytes from embryonic stem cells as a means to characterise receptor/ channel expression in human tissue
Nurture (0076)
Interim Inspection

Members:	In Attendance:
Emily Jackson – Chair, Lay Member	Chris O'Toole, Head of Research Regulation
Richard Harries, Lay Member	Claudia Lally, Committee Secretary
Clare Brown, Lay Member	Joanne McAlpine, Inspections, Logistics and Reporting Officer
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	
Neva Haites, Professor of Medical Genetics, University of Aberdeen	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 papers were considered by the Committee:

- papers for Licence Committee (43 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 has not been fully operational since April 2007 when the centre moved to new laboratories in a separate building within the same university/hospital complex as the current licensed premises. Dr O'Toole added that the Committee is asked to consider whether a second licence is needed for the new laboratories.

2. Another issue raised in the inspection report is that the focus of one aspect of the research has changed since the inception of the project in 2004. Notably, the third objective of the project, as originally licensed, has ceased to be a main experimental focus. This project involved the characterisation of receptors in cardiomyocytes and smooth muscle cells as derived from stem cells. Dr O'Toole asked the Committee to consider whether the lay summary of the project should

be varied or whether the change in focus necessitates the relicensing of the project.

3. Another key finding was that the centre plans to change the way the project is being conducted, and intends to use embryos donated by patients receiving NHS-funded treatment. This will make it necessary for the project to receive Local Research Ethics Committee (LREC) approval.

Legal Advice Received

4. In relation to the question as to whether a second licence was required for the new laboratories, the Legal Adviser took the Committee to Schedule 2, paragraph 4(2)(d) of the Human Fertilisation and Embryology Act 1990 which states that a licence cannot apply to premises in "different places". The question for the Committee was therefore whether the new laboratories are in a "different place" from the licensed premises.

The Committee's Decision

5. On the basis of the description of the location given by the inspector the Committee agreed that they were satisfied that the new laboratory facilities are contained within the University medical complex and therefore, despite being in a different building, do not count as being at a different place under the Human Fertilisation and Embryology Act 1990. Consequently, the Committee decided that the new facilities are covered under the project's current licence. On the basis of the information received in the report the Committee agreed that they were happy for work to commence in these new premises. However, the Committee noted with concern that HFEA licensed work was begun in these facilities prior to their receiving HFEA approval.

6. The Committee noted that the centre does not have appropriate LREC approval for the work they are currently undertaking. The Committee reminds the centre that no NHS patients can be approached to donate material until such time as this approval has been received.

7. The Committee endorsed the recommendations in the inspection report. In particular, the Committee endorsed the recommendation that protocols should be revised to state that viable embryos should not be left unattended in shared laboratory areas. The Committee also noted the reservations expressed by the staff of the project about the security of consent forms held by the secretary of the National Stem Cell Bank. The Committee endorsed the recommendations of the inspection team that the Person Responsible seeks guidance from the NSCB on the security of consents and ensures compliance with standard licence condition (3)(e)ii which requires them to send non-anonymised consent forms to the NSCB.

8. In relation to the change of focus of the research project, the Committee agreed that they were satisfied that the aims of the research were sufficiently close to the original stated aims of the project to justify its continuing under the same licence.

9. The Committee agreed that the licence for this project of research should continue with no additional conditions.

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