Research Licence Committee Meeting

13 September 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Research Project R0167: Disaggregation of embryos for the purpose of deriving stem cells from human surplus embryos
Based at Bourn Hall Clinic (0100)
Licence Renewal

Members:
Ivor Brecker, Lay Member – Chair
Richard Harries, Lay Member
Clare Brown, Lay Member
Neva Haites, Professor of Medical Genetics, University of Aberdeen
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Secretary to the Committee

Providing Clinical Advice:
David Barlow, Executive Dean of Medicine, University of Glasgow

Observing:
Mr Stephen Yau and Professor Christopher Haines, Members of the Hong Kong Council on Human Reproductive Technology

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 (32 pages)
- no papers were tabled.

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that the role of the centre is to provide embryos and develop them to blastocyst stage, in preparation for stem cell derivation at the University of Cambridge. Because the protocols for this research project are the same as those used for clinical treatment they were not sent for approval by a peer reviewer.

2. The Committee noted page six of the inspection report which states that the Person Responsible, who is not involved in the clinical treatment of the patients, is responsible for recruitment of patients to this research project. The Committee agreed that it was important to ensure a separation between clinical and research roles.

3. The Committee asked Dr Lamb whether there is any possibility that participation in the research project might be compromising the quantities of embryos frozen for patients' future use. Dr Lamb replied that the centre has only applied to use frozen embryos in the research, and these will be embryos which patients no longer wish to keep in storage.

4. The Committee agreed that the activity to be licensed is the disaggregation of embryos for the purpose of deriving stem cell lines under research licence RO162.

5. The Committee agreed that these activities appear to be necessary or desirable for the following specified purposes:

- Human Fertilisation and Embryology (Research Purposes) Regulations 2001:
  2(2)(a) Increasing knowledge about the development of embryos,

- Human Fertilisation and Embryology (Research Purposes) Regulations 2001:
  2(2)(c) Enabling any such knowledge to be applied in developing treatments for serious disease.

The above purposes were the purposes under which the research project R0162 was licensed. Members of the Committee agreed that because the proposed research project will be supplying embryos to R0162, then it should be licensed in relation to the aims and purposes of RO162 which is attempting not only to develop hES cultures, but also to characterise the factors of an embryo which are necessary for good embryonic development and to produce stem cell lines for use in future treatments for serious disease.

6. The Committee agreed that they were satisfied that the proposed use of human embryos is necessary for the purpose of the research.

7. The Committee noted that the patient information and consent forms have not changed since they were approved last year.

8. The Committee were satisfied that the requirements for granting a licence under section 16 of the Human Fertilisation and Embryology Act 1990 were fulfilled, other than the payment of the licence fee. However, it was noted that the

centre has not yet been invoiced for this fee. The Committee therefore agreed that they were minded to grant a three year licence for the research, with the proviso that the centre pays its licence fee and that it submits evidence that there is a clear separation between consenting patients for treatment and for donating to research.

Signed…… … Date……..
Ivor Brecker (Chair)