

HFEA Research Licence Committee Meeting
15 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

IVF Hammersmith (0078; R0187) – Renewal

Members of the Committee:

Emily Jackson (lay) – Chair
Richard Harries (lay)
David Archard (lay)
Lesley Regan (clinician)

Committee Secretary:
Kristen Veblen

Legal Adviser:
Sarah Ellson, Field Fisher
Waterhouse

Declarations 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 (68 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

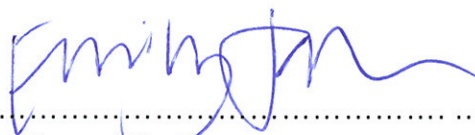
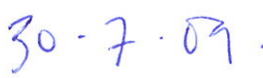
1. The Committee noted that the research project had commenced on 19 November 2008, that the current licence would expire on 30 September 2009, and that the renewal application had been made for 2 years.
2. The Committee considered the papers, which included the renewal inspection report, a peer review, related correspondence and Licence Committee minutes from 16 September 2008 and 19 November 2008.
3. The Committee noted that the renewal inspection had taken place on 28 April 2009 and that the PR had responded to the report on 18 June 2009. The Committee also considered the additional correspondence responding to the peer review, clarification of the response to the report and ethics committee approval.
4. The Committee noted the issue around the notification of patients regarding the disposal of their embryos raised by the report and were satisfied with the response of the Person Responsible.
5. Also, the Peer Reviewer had raised concerns about power calculations, however, the Committee noted that this study was only a pilot study and again were satisfied with the response of the Person Responsible. In any event, the Peer Reviewer had indicated that they were satisfied that the licence application should be accepted in its current form.

The Committee's Decision

6. The Committee identified the activities to be authorised by a licence as storage of embryos and use of donated embryos for research. The Committee agreed that they were satisfied that these activities were not prohibited under the HFE Act 1990 (as amended).
7. The Committee decided that these activities were necessary and desirable for the following purposes:
 - promoting advances in the treatment of infertility
HFE Act 1990 (as amended) 2 3(2)(e)
 - developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation
HFE Act 1990 (as amended) 2 3(2)(e)
8. The Committee decided that it was satisfied that the proposed use of human embryos was necessary for the purpose of research. In making this decision the Committee took into account that the purpose of the project was to determine whether vitrification would be a viable method for the cryopreservation of biopsied multiple cells. The Committee agreed that the use of human embryos was necessary and desirable, as it would not be

possible to accurately determine the effect of this method on human embryonic cells, without using those cells in the research.

9. The Committee noted that the patient information and consent forms had not changed since the original application for this project and that these forms remained fit for purpose.
10. The Committee considered itself satisfied that it was appropriate to grant a licence, noting that it was in possession of an application from the Centre and that the appropriate fee had been paid.
11. The Committee agreed that it continued to be satisfied as to the character, qualifications and experience of the Nominal Licensee. Also, the Committee agreed that it also continued to be satisfied as to the character, qualifications and experience of the Person Responsible as required for the supervision of the activities to be discharged under Section 17 of the HFE Act 1990 (as amended).
12. Further, the Committee agreed that it continued to be satisfied that the premises for which the Licence was to be renewed, as described by the report, were suitable for the activities.
13. The Committee, in accordance with the recommendation of the Executive, decided to grant a licence for a period of two years, with no additional conditions.

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