

HFEA Licence Committee Meeting

26 June 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0035 (Oxford Fertility Unit) – Research Variation Change of Research Activities and Project Title

Members of the Committee: Dr Andy Greenfield (lay) Chair Bishop Lee Rayfield (lay) Professor David Archard (lay) (videoconference)	Legal Adviser: Tom Rider, Fieldfisher
Committee Secretary: Lauren Crawford	Also in Attendance: Sam Hartley, Head of Governance and Licensing

Declarations of Interest: members of the Committee present declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- Executive summary
- Application form
- Anonymised Peer Review including response from the Person Responsible (PR)
- Previous licensing minutes for the last three years:
 - 13/09/2012 Licence renewal
- Revised Peer Review form (tabled)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation

- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. An application for a new research licence from Oxford Fertility Unit was received on the 28 February 2014; additional information compliant with Directions 0008 paragraph 12 was received in support of the application.
2. The centre is currently licensed for a project entitled: 'Development of a model to study implantation in the human'. (R0111). Following discussions with the PR, it was agreed that the application should be treated as a variation of the centre's existing licence to reflect the extension of the proposed research to include an additional research objective, rather than a new licence application.

Discussion

3. The Committee noted that the PR, Dr Karen Turner will remain as PR of the project, and that the variation application does not propose any change to the premises where the research will be carried out. These research premises were considered suitable following an interim inspection in May 2014 that took into consideration this application.
4. The Committee noted that the objectives of the current research are as follows:
 - Detection of molecules involved in the implantation process in pre-, peri- and post-implantation embryos; the implantation models will be used to investigate aspects of human embryo implantation.
5. The Committee noted that the proposed additional research objective is:
 - To test the ability of human recombinant PLCzeta protein to cause activation in human eggs that have previously failed to activate. To improve selection of viable eggs and embryos for transfer back to mothers by investigating cytoplasmic movements in the activating oocyte.
6. The Committee noted that that the centre's current licence permits the following activities:
 - storage of embryos
 - keeping embryos
 - use of embryos

7. The Committee noted that the original application stated that the newly proposed research would only require the use of oocytes. Since submitting the application, the PR has confirmed that oocytes will be parthenogenetically activated. Embryos generated by parthenogenetic activation of oocytes are considered to fall within the definition of 'embryo' (section 1, paragraph (2)(a) of the HF&E Act 1990, as amended), and therefore the PR has confirmed that the newly proposed research will also require the activity 'creation of embryos' to be added to the centre's licence.
8. The Committee noted that the proposed title of the amended research project would be 'Artificial oocyte activation and egg/embryo movements as early indicators of embryo quality, and development of a model to study implantation in the human'.
9. The Committee noted that the licence was granted on the basis that it appeared to the authority to be necessary or desirable for the following principal purposes (Schedule 2, Section 3A (2) of the HF&E Act, 1990, as amended):
 - (d) promoting advances in the treatment of infertility
 - (e) increasing knowledge about the causes of miscarriage
 - (h) increasing knowledge about the development of embryos
10. The Committee noted the Executive's recommendation to vary the centre's licence by:
 - adding the additional research objective
 - adding the additional research activity
 - changing the title of the research project

Consideration

11. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted in the form required. The Committee noted that the application was made by the Person Responsible for this research project.
12. The Committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the proposed additional licensed activity, for the reasons given when the licence was renewed.
13. The Committee was satisfied that the premises to be licensed are suitable for the conduct of the proposed additional licence activity.
14. The Committee noted the new tabled Peer Review and accepted it as supportive of the application.
15. The Committee was satisfied that the further activity to be licensed is necessary or desirable for the following purpose, which already appears on the centre's licence:

(d) promoting advances in the treatment of infertility

Decision

16. The Committee agreed to vary the centre's licence to change the title of the project to 'Artificial oocyte activation and egg/embryo movements as early indicators of embryo quality, and development of a model to study implantation in the human'.
17. The Committee agreed to add the additional objective 'To test the ability of human recombinant PLCzeta protein to cause activation in human eggs that have previously failed to activate. To improve selection of viable eggs and embryos for transfer back to mothers by investigating cytoplasmic movements in the activating oocyte'.
18. The Committee agreed to add the additional activity of 'creation of embryos'.

Signed:

Date: 09/07/2014

A handwritten signature in black ink, appearing to read 'AGF', is written over a faint dotted line.

Dr Andy Greenfield (Chair)