HFEA Research Licence Committee Meeting

19 November 2012

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

Minutes – Item 1

Centres 0033 (Manchester Fertility Centres), 0067 (St Mary's Hospital) and 0175 (University of Manchester) - Renewal Inspection Report for Research Project R0026

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair Andy Greenfield (lay) Neva Haites (professional)	Lauren Crawford Legal Adviser: Stephen Hocking, DAC Beachcroft LLP

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:

- Renewal inspection report
- Application form for 0175
- Application form for 0067
- Application form for 0033
- Publication
- Peer review
- Previous Licence Committee minutes for the last three years:
    - Interim inspection report 2 December 2011
    - Variation of premises 8 April 2011
    - Resubmission of application for centre 0033 15 September 2010
    - Resubmission of application for centre 0067 15 September 2010
    - PR's position on renewal application 10 March 2010
    - Special Directions 9 December 2009
    - Renewal inspection report 18 November 2009

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)
- 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. Research project R0026 is carried out at three different centres, each centre holding a research licence for this project. Centre 0175 is a research only centre and centres 0067 and 0033 are treatment and storage with research centres.

2. The current research project, entitled "In-vitro development and implantation of normal human pre-implantation embryos and comparison with uni- or poly-pronucleate pre-embryos" (R0026), was first licensed in June 1996. The licence is due to expire on 31 January 2013 at centre 0175 and on 31 December 2012 at centres 0067 and 0033.

Consideration

3. The Committee noted that the report covers the pre-inspection analysis, a desk based evaluation of the applications and supporting information and information received between 16 September 2011 and 5 November 2012.

4. The Committee noted that at the time the renewal inspection took place there were no areas of non-compliance that had been identified by the inspectorate that required improvement.

5. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted in the form required, and noted that the executive has had the chance to review the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fee had been paid. The Committee noted that the application was made by the proposed Person Responsible ("PR") for Research.

6. 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 licensed activities. It was further satisfied that the PR will discharge her duties under section 17 of the Act. The Committee noted that the Inspector was satisfied the PR had satisfactorily completed the PR entry programme and is suitably qualified and experienced to undertake the role.

7. The Committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities as the Inspector confirmed that the premises were suitable and secure.

8. The Committee was satisfied that the licence application involved the authorisation of activities for the purpose of research.

9. The Committee was satisfied that the renewed licences would not apply to more than one project and that the activity of the licence, permitted under the Act, is for 'creation of embryos in vitro', 'keeping embryos', 'storage of embryos' and 'the use of embryos for research'.

10. The Committee was satisfied that the use of human embryos is necessary because the project involves the study of molecules and cells of normal and abnormal human embryonic development and thus requires the use of human embryos.

11. The Committee noted the Peer Reviewer's support for the application and was satisfied that the activity to be licensed is necessary or desirable for the following purposes, specified in Schedule 2 paragraph 3A(2) to the Act, for the following reasons:

    - *Promoting advances in the treatment of infertility* (Schedule 2 paragraph 3A(2)(d) to the Act): The reason for this is: The aim of the project is to understand the way in which human embryos develop normally and abnormally in culture and thus may give further information on the causes of infertility.
    - *Increasing knowledge about the cause of miscarriage* (Schedule 2 paragraph 3A(2)(e) to the Act): The reason for this is: Understanding how intrinsic and extrinsic factors impinge on human embryonic cells and therefore how miscarriage can be caused.
    - *Developing more effective techniques of contraception*(Schedule 2 paragraph 3A(2)(f) to the Act): The reason for this is: 'Understanding early human embryo development and the regulation of cell fate and pluripotency may be relevant to developing interventions which might prevent embryo development,

implantation, or subsequent development and thus aid the development of embryos and abnormalities that can occur.

- *Increasing knowledge about the development of embryos (Schedule 2 paragraph 3A(2)(h) to the Act):* The reason for this is: The aim of this project is to understand the way in which human embryos develop normally and abnormally in culture. In particular, this includes the study of the regulation of cell fate in embryos, in terms of survival or apoptosis, maintenance of pluripotency, and differentiation/cell lineage specification, and expression of molecules involved in the implantation process. Another focus concerns how the in vitro environment and IVF manipulations impact on this, for example, the way in which growth factors regulate cell fate, the influence of DNA damage in sperm on embryonic development, or the impact of cryopreservation on embryonic development and gene expression.

12. The Committee was satisfied that the proposed project does not involve mixing sperm with the egg of an animal.

13. The Committee was satisfied that the inspector had previously seen the patient information and consent forms, and that these met the statutory requirements.

14. The Committee was satisfied that the research project had received the necessary approval from the centre's own Research Ethics Committee.

15. The Committee noted the recommendation from the Inspectorate to renew the centre's research licence for a period of 3 years without additional conditions.

Decision

16. The Committee agreed to renew the research licences for project (R0026) at centres 0033, 0067 and 0175 for a period of three years with no additional conditions

Signed:  Date: 17/12/2012

Sally Cheshire (Chair)