HFEA Research Licence Committee Meeting

19 November 2012

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

Minutes – Item 2

Centres 0033 (Manchester Fertility Centres), 0067 (St Mary's Hospital) and 0175 (University of Manchester) - Renewal Inspection Report for Research Project R0170/R0171

Members of the Committee: Sally Cheshire (lay) Chair Andy Greenfield (lay) Neva Haites (professional)	Committee Secretary: 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 R0170/R0171 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 “Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos” (R0170/R0171), was first licensed in August 2006. There are two research project numbers as the project was first licensed at centre 0033 and then at centre 0067. As two centres were involved, even though the project was the same, two project numbers were issued. The licence is due to expire on 31 December 2012.

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 two areas of practice that required improvement, including one major area of non-compliance and one ‘other’ area of non-compliance or poor practice.

5. The Committee noted that the PR has confirmed that the recommendation for the ‘other’ area of non-compliance or poor practice has been fully implemented.

6. The Committee noted that the recommendation in regards major area of non-compliance was being challenged by the centre. The recommendation is
    - The PR should ensure that the full range of serological tests required by the Human Tissue Authority (HTA) standards are performed on patients donating material to this research project (Standard Licence Condition R66).

7. The Committee noted the PR's response to the recommendation that 'This is not possible as we do not have ethical approval to perform blood tests which are not part of routine IVF patient screening. This has been discussed in detail with the HFEA and HTA and in fact the HTA have a consultation out on this at the moment. I will bring this to the attention of the HTA and the National Clinical human Embryonic Stem cell forum which involves all of the derivation centres in the UK'.

8. The Committee further noted the Executives review statement 'Following the consultation, the HTA is proposing to ask the other European Competent Authorities to support a submission to the European Commission to request amendments be made to the EUTCD in relation the testing requirements for embryonic stem cell lines. The HFEA has supported this submission'.

9. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted in the form required, and note 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.

10. 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 his 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.

11. 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.

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

13. The Committee noted that the project is currently licensed for the research purposes; 'Increasing knowledge about serious disease or other serious medical conditions', 'Developing treatments for serious disease or other serious medical conditions', 'Promoting advances in the treatment of infertility' and 'Increasing knowledge about the development of embryos'.

14. The Committee noted that the PR has applied to add two further research purposes 'Increasing knowledge about the causes of miscarriage' and 'Developing more effective techniques of contraception.

15. 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'.

16. The Committee was satisfied that the use of human embryos is necessary because adult stem cell line(s) or induced pluripotent stem cells (IP's) cells cannot be adequately substituted for human embryonic stem cells.

17. 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:

    - *Increasing knowledge about serious disease or other serious medical conditions* (Schedule 2 paragraph 3A(2)(a) to the Act): the derivation of human embryonic stem (ES) cells may provide insight into disease or medical problems by virtue of the information gained from studying cell fate and cell communication.
    - *Developing treatments for serious disease or other serious medical conditions* (Schedule 2 paragraph 3A(2)(b) to the Act): The derived human ES cell lines are intended to provide clinical grade tissue that may be suitable for cell replacement therapy.
    - *Promoting advances in the treatment of infertility* (Schedule 2 paragraph 3A(2)(d) to the Act): ES cells are commonly used as an in vitro model for embryonic development. The applicants expect to address problems in embryo development, using human ES cells, that may be relevant to fertility treatment.
    - *Increasing knowledge about the cause of miscarriage* (Schedule 2 paragraph 3A(2)(e) to the Act): The regulation of cell fate and pluripotency that can be studied using human ES cells may be a contributory factor to normal development. When such processes break down it may be anticipated that an embryo may be aborted.
    - *Developing more effective techniques of contraception*(Schedule 2 paragraph 3A(2)(f) to the Act): It is anticipated that the knowledge gained from studying human ES cells as a model for human development may inspire treatments that could inhibit the

development of embryos, thereby providing an alternative form of contraception.

- *Increasing knowledge about the development of embryos (Schedule 2 paragraph 3A(2)(h) to the Act):* ES cells are commonly used as a model for early human development. This knowledge will be directly applicable for human development in vivo.

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

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

20. The Committee was satisfied that the research project had received the necessary approval from the centres own Research Ethics Committee.

21. 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

22. The Committee agreed to renew the research licences for project (R0170/R0171) at centres 0033, 0067 and 0175 for a period of three years with no additional conditions.

Signed:  Date: 17/12/2012

Sally Cheshire (Chair)