

HFEA Research Licence Committee Meeting

15 September 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0033 – Resubmission of signed research renewal application for research project R0170

Members of the Committee:	Committee Secretary:
Emily Jackson (lay) – Chair	Terence Dourado
Andy Greenfield (Professional)	Legal Adviser:
Neva Haites (Professional)	Sarah Ellson, Field Fisher
Clare Lewis-Jones (lay)	Waterhouse 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:

- Executive Summary
- Signed research renewal application form for research project R0171
- Correspondence from research Person Responsible 27 July 2010
- Research Licence Committee minutes 10 March 2010
- Licence Committee minutes 09 December 2009
- Research Licence Committee minutes 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 R0170/1 (“Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos”) had previously been carried out at three separate locations (namely licensed centres 0175, 0067 and 0033). Professor Daniel Brison is the Person Responsible (PR) for all the licensed Centres.
2. On 18 November 2009 the Research Licence Committee met to consider renewal of licences in respect of research project R0170/1 (alongside R0026). The application form presented to the Committee, whilst referring to all three Centres, was signed by Professor Brison, as PR and Dr Susan Kimber, as Nominal Licensee (Licence Holder) for centre 0175 .The Committee agreed to renew the licences in respect of centre 0175 with no additional conditions on the basis that a completed application form had been provided from that particular Centre. The Committee deferred consideration of the applications in respect of Centres 0067 and 0033 pending submission of completed renewal application forms signed by the Nominal Licensees (Licence Holders) from those Centres.
3. On 9 December 2009, at a further meeting of the Research Licence Committee, Special Directions were issued under Section 24(5A) of the Act to Centres 0067 and 0033. The Special Directions were issued for a period of three months (31 December 2010 until 31 March 2010) to enable research work to continue at Centres 0067 and 0033 whilst the position in relation to the licences for those Centres was resolved. The Research Licences in respect of those Centres expired on 31 December 2009.
4. The Committee, which met on 17 March 2010, agreed it would be sufficient in the circumstances of this case for the proposed Licence Holder for Centre 0033 to sign a copy of the original applications submitted for Centre 0175 because the research projects are the same, and all three centres (0033, 0067 and 0175) have been inspected by the Authority.
5. The Committee requested a further copy of each of the original applications forms, with amended centre number (0033) and the signature of the Licence Holder. The Committee noted, although the current fee structure is under review by the Authority, no additional fee is required from the Centre in relation to the renewal application
6. The Committee agreed that, subject to the signed applications being received, a licence could be issued to Centre 0033 in respect of the research project on the same terms as offered to Centre 0175.

Consideration of Application

7. For the reasons it granted Centre 0175 a licence on 18 November 2009 (in italics below) the Committee, having now received the appropriate application form signed by the PR and LH, agreed that the requirements of the decision tree in respect of the renewal of research licence R0170 had also been satisfied. The Committee was equally satisfied about the suitability of the premises at Centres 0033 on the basis of the joint inspection report previously presented to it.
8. *The Committee applied the licensing decision tree in consideration of the application for the renewal of the licence for centre 0175.*
9. *The Committee identified the activities to be licensed as the storage of sperm; storage of embryos; creation of embryos; use of donated embryos and derivation of embryonic stem cell lines. The Committee agreed that they were satisfied that these activities are not prohibited under the Human Fertilisation and Embryology Act 1990 (as amended).*
10. *In considering stage 18(a) of the decision tree which requires that the activity is necessary and desirable for the purposes specified in paragraph 3A(2) of Schedule 2 to the Act, the Committee considered the purposes of the research project in relation to these requirement.*
11. *The Committee agreed that the activities are necessary or desirable for the following specified purposes:*
 - *Promoting advances in the treatment of infertility (HFEA Act 1990 (as amended) Schedule 2 3A(2)(d))*
 - *Increasing knowledge about the development of embryos (HFEA Act 1990, as amended Schedule 2 3A(2)(h))*
 - *Increasing knowledge about serious disease (HFEA Act 1990, as amended Schedule 2 3A(2)(a))*
 - *Enabling any such knowledge to be applied in developing treatment for serious disease (HFEA Act 1990 as amended Schedule 2 3A(2)(b))*
12. *The Committee was satisfied that the proposed creation and use of embryos is necessary for the purposes of the research. The Committee agreed that the present evidence shows that with current methodology to derive human IPS cells the resulting cells differ from human embryonic stem cells and currently have unknown potential for use therapeutically. Adult stem cells are also not suitable for these purposes.*
13. *The Committee was satisfied that ethics committee approval for the research project had been received.*

14. The Committee noted that the Special Directions, which it had extended until 31 May 2010, expired before the PR submitted this application. However, the Committee noted that this was due to an administrative oversight at the Centre. The PR has reassured the Executive that no research work was conducted at Centre 0033 following the expiry of these Special Directions.
15. The Committee agreed to grant the Research Licence until 31 December 2012 so that research project R0170 at Centre 0033 can be renewed at the same time as the research projects at centre 0067 and centre 0175, which are due to expire on this date.

Signed:

Date:



24.9.10

Emily Jackson (Chair)