

HFEA Research Licence Committee Meeting

10 March 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0067 and 0033 – Paper explaining PR’s position on application renewal for projects R0026 & R0170/1

Members of the Committee:
Emily Jackson (lay) – Chair
Andy Greenfield (Professional)
Clare Lewis-Jones (lay)
Lesley Regan (Professional)

Committee Secretary:
Terence Dourado

Legal Adviser:
Graham Miles, Morgan Coles

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
- Research Licence Committee minutes 18 November 2009
- Licence Committee minutes 09 December 2009
- Special Directions for R0026 & R0170/1 (09/12/2009)
- Correspondence from research Person Responsible 25 January 2010
- Original research renewal application forms for research projects R0026 & R0170/1
- Offer licence R0171

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

Tabled documents

- Papers from the Research Licence Committee meeting held on 18 November 2009 (Centre 0067; 0175;0033 - Renewal Report).
- Minutes from Research Licence Committee held on 29 November 2009 (Item 5) and 15 January 2009 (Item 3 and 4)

Background

1. Research Projects R0026 and R0170/1 have previously been carried out at three separate locations (namely licensed centres 0175, 0067 and 0033). Professor Daniel Brison is the Person Responsible (PR) for each of the licensed centres.
2. On 18 November 2009 the Research Licence Committee met to consider renewal of licences in respect of each project. 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 2009 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.

Responses from Centres 0067 and 0033

4. The Committee received the PR's response to the minutes of 18 November 2009 which stated that they had submitted one renewal application on behalf of Centres 0175, 0033 and 0067, and that it was incorrect to minute that the applications were only received from Centre 0175. Furthermore, the PR stated that licences had previously been issued

for more than one site and joint renewal application forms had always been submitted in the past.

Legal Advice

5. The Legal Adviser advised the Committee that the effect of Paragraph 4 of Schedule 2 to the 1990 Act, as amended, in the context of this case was that:
 - Separate licences are required in respect of each of the projects of research R0026 and R017/1
 - There is no prohibition on granting more than one licence for a single research project.
 - A licence can only authorise licensable activity to be carried out on premises specified in the licence unless the activity is one which may be carried out on relevant third party premises. The activities of bringing about the creation of embryos in vitro or the keeping or using of embryos for the purposes of a project of research are not activities which can be carried out under a third party agreement on third party premises. (See sections 3(1A) and (1B), 4 (1A) and 12 (1) (aa).
 - A single licence cannot apply to premises in different places (paragraph 4(2)(d).
 - Although the premises of the 3 centres are all located in Manchester, they are all in different geographic locations within that city and in different places for the purposes of paragraph 4(2)(d).
 - It followed that, in respect of each research project, if creation, keeping or using of embryos is to take place at each centre, even though under the same research project, a separate licence is required to conduct that activity at each centre.
6. The Legal Adviser further advised that on 18 November 2009 the Research Licence Committee was not able to grant licences to centres 0067 and 0033 as no signed application forms had been submitted by the proposed Licence Holders in respect of either of those centres as required by section 16 (2) of the Act even though the application was intended to apply to all 3 centres.
7. The response from the Centre suggested that a licence had previously been granted and/ or renewed to cover more than one site. Unfortunately, however, this was not an area in which the Act gave the Committee any discretion to grant a single licence by way of renewal authorising licensable activity at more than one centre.

Decision

8. The Committee agreed that the requirements of the decision tree for the renewal of research licences R0026 & R0170/1 had been satisfied in relation to Centre 175 and the Committee was satisfied about the

suitability of the premises at Centres 0033 and 0067 on the basis of the joint inspection report previously presented.

9. The Committee accepted that it was bound by the legal advice that separate licences were required in relation to each of the centres and that the proposed Licence Holders for Centre 0033 and 0067 must sign application forms for research projects R0026 and R0170/1 before licences can be issued in respect of those Centres.
10. The Committee agreed it would be sufficient in the circumstances of this case for the proposed Licence Holders for Centre 0033 and 0067 to sign a copy of the original applications submitted for Centre 0175 because the research projects are the same, and all three centres have been inspected by the Authority. All the Committee requires, therefore, is two further copies of each of the original applications forms, with amended centre numbers (0033 and 0067) and the signatures of the Licence Holders in each of these centres. The Committee noted, although the current fee structure is under review by the Authority, no additional fee is required from either Centre in relation to these renewal applications.
11. The Committee agreed that, subject to the signed applications being received, licences could be issued to Centres 0033 and 0067 in respect of both research projects on the same terms as offered to Centre 175.
12. The Committee agreed that the Special Directions should be extended beyond the expiry of the existing directions on 31 March 2010 to give the Person Responsible and the proposed Licence Holders an opportunity to consider the explanation contained within the legal advice to the Committee and sufficient time to submit the signed application forms. The Committee considered it appropriate to issue directions for a further two months until 31 May 2010.
13. The Committee noted that the licence offer for project R0171 had omitted from its purposes the 'treatment of serious disease' in relation to the research project's purposes. The Committee agreed that this purpose was approved on 18 November 2009, as confirmed by the minutes of that meeting. Although this did not affect the validity of the offer previously sent, the Committee agreed that Annex D of the licence offer 'Purpose of Research Project' for R0171 at Centre 0175 should be reissued with the additional purpose included.

Signed:

Date:



17.3.10

Emily Jackson (Chair)