

HFEA Research Licence Committee – Consideration of Written Representations

15 December 2011

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

Minutes – Item 1 – Consideration of Written Representations

Centre 0049 IVF Wales

Members of the Committee: Emily Jackson (lay) – Chair Neva Haites (Professional) Sally Cheshire (lay) – (by teleconference)	Committee Secretary: Lauren Crawford Legal Adviser: Rosalind Foster, DAC Beachcroft LLP
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Preliminary matters

One of the members of this committee was originally due to attend the meeting via video conference. Due to technical issues the connection was unable to be made. Without the attendance of this member, the Committee would be inquorate and the meeting would have to be rescheduled.

The Chair asked the Legal Adviser whether it would be possible for the meeting to go ahead with the member on a teleconference rather than further delay the meeting.

The Legal Adviser advised that there was nothing in the Protocol for meetings of the Research Licence Committee nor the relevant Regulations¹ that prohibited the attendance of a Committee member by telephone. Regulation 3(7) provides that, subject to those Regulations and the Act, the Committee could regulate its own proceedings. The Chair and the Committee members were content to proceed by way of teleconference. The meeting had been convened to consider written representations in relation to the proposed variation of a licence. The Person Responsible had declined the option of an oral hearing. In the circumstances, the Legal Adviser advised that the meeting could be conducted by way of teleconference and that to do so would not cause the Person Responsible or the Centre any prejudice. Having considered that advice, the Committee resolved to proceed with the meeting with the third member of the Committee on the telephone.

¹ The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009

The following papers were considered by the Committee:

- Notice of Representations -24 November 2011
- Licence Committee (LC) papers re incident report for centre 0049
- LC minutes – 20 October 2011
- Offer Licence letter and acknowledgment form – 25 October 2011
- Notice of Proposal to Vary Licence – 25 October 2011
- Offer licence variation – L0049-14-e – 25 October 2011
- HF&E (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009
- Emailed correspondence between PR and LC chair via LC secretary
- Request to make written representations from PR of centre 0049
- Response to an offer of a licence
- Written representations against a condition placed on offer licence
- Appendix 1: Extract from centre 0049's dashboard to show how activity is monitored)
- Additional emailed correspondence from the PR of 0049
- Email from the inspector (case officer) regarding submission to the committee
- Confirmation of representations date emailed to the PR of centre 0049

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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.

Procedure

1. The Notice of Hearing was served in accordance with the required time frame. The procedure was governed by the Human Fertilisation and Embryology Act 1990 (as amended); The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 and the Protocol for the Conduct of Licence Committee Meetings and Hearings approved by the Authority on 21 January 2009.
2. The Committee considered it had no conflicts of interest in relation to the hearing and the Chair confirmed that the Committee was quorate.

Background

3. Centre 0049 has been licensed since 1992 and its last licence was issued on 15 July 2010 for a period of two years.

4. The Licence Committee, which met on 20 October 2011, had received an incident inspection report for centre 0049. The Licence Committee decided, on the basis of the inspection report and peer review findings, to vary the centre's licence and impose the following condition:
 - The Centre must limit the number of IVF or ICSI cycles provided to six cycles per week in total and of frozen embryo transfers two per week in total.
5. On the 25 October 2011 an offer of a licence (L0049-14-e) was sent to the PR of centre 0049 alongside an acknowledgement form and the LC minutes of the 20 October 2011.
6. The PR, on the 11 November, sent in a letter of non-acceptance for the varied licence. The PR also submitted a written representation to be considered, in which she accepted the purpose of the condition and the principle of the imposition of a condition to achieve that purpose, but explained the reasons why she did not agree with the wording of the condition that had been proposed.

Consideration

7. The Committee noted the PR has acknowledged the condition and the reasons for it being put in place. The PR was not opposing the condition itself, but had requested that the wording be amended.
8. In her written representations, the PR went on to explain why the condition as drafted did not reflect good clinical practice. The duty of care owed to patients required the PR to collect eggs and transfer embryos at the time that was in the best interests of the individual patient. This requires some flexibility in scheduling egg collections and embryo transfers. The PR stated that the proposed condition would increase the chances of the Centre having to abort treatments should the number of treatments in any given week exceed the prescribed limits.
9. The Committee noted the evidence provided by the Centre which showed that it had been working at a reduced activity level as a result of advice from the Executive.
10. The Committee noted that the Centre's PR was appointed in June 2011 and that she was striving to comply with the Executive's recommendations.
11. The Legal Adviser explained that the remit of the Committee was not to review the whole of the Licence Committee's previous decision (which included various recommendations to the Executive as to matters to be considered at the next inspection) but simply to consider whether the licence

should be varied, having regard to the decision of the Licence Committee and the representations made by the PR. The Committee were reminded that a licence could not be varied unless the circumstances were such that the Authority could revoke the licence, and that any decision taken must be fair and proportionate. The Legal Adviser confirmed that the PR would be notified of the Committee's decision, and had a right of appeal against that decision.

Decision

12. The Committee acknowledged and understood the purpose of the condition and agreed that limiting the activity in the Centre was important in order to ensure that the licensed activities undertaken at the Centre were carried out safely and to maintain confidence in the conduct of licensed activities at the Centre.
13. The Committee also accepted that placing a limit on the number of cycles to be carried out on a weekly basis may not be consistent with good clinical practice.
14. As a result, the Committee decided not to vary the licence in accordance with the decision of the Licence Committee, but to vary the licence so as to apply a differently worded condition that would achieve the same outcome whilst allowing the Centre the flexibility necessary to provide a good standard of clinical care for patients.
15. The new condition to be applied for the remainder of this licence (until 30/12/2012) is:
 - For the remainder of the licence, and calculated over a six-month period, the Centre must limit the number of IVF or ICSI cycles provided to an average of twenty-four cycles per calendar month in total, and of frozen embryo transfers to an average of eight per calendar month in total.

Signed:

Date: 16/12/2011

A handwritten signature in black ink, appearing to read 'Emily Jackson', with a long horizontal flourish extending to the right.

Emily Jackson (Chair)