

HFEA Licence Committee

9 May 2013

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

Minutes – Item 5

Centre 0325 (Bourn Hall Clinic (Norwich)) – Variation of Licence – to Remove Licence Condition

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair	Lauren Crawford
Andy Greenfield (lay)	Rebecca Loveys (observing)
Debbie Barber (professional)	
Bishop Lee Rayfield (lay)	Legal Adviser:
Gemma Hobcraft (lay)	Stephen Hocking, DAC Beachcroft

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
- Initial Inspection Report
- Minutes of the last Licence Committee Meeting 28 March 2013
- Application to vary the licence from the Centre

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); and
- 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
- HFEA Pre-Implantation Diagnostic Testing (“PGD”) Explanatory Note For Licence Committee

Discussion

1. The Committee noted that an Initial Application for Treatment and Storage licence from Bourn Hall Clinic (Norwich) (Centre 0325) was previously considered by the Licence Committee on the 15 April 2013.

2. The Committee noted that at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including three major areas of non-compliance and three ‘other’ area of non-compliance or poor practice which were:

‘Major’ areas of non-compliance:

- The PR should ensure all critical procurement and processing procedures are validated prior to treatment being offered.
- The PR should ensure the air quality in the processing areas is assessed and meets the requirements of Standard Licence Condition (SLC) T20 before treatment is offered.
- The PR should ensure that critical equipment, instruments, devices and other consumables to be used during the procurement and processing of gametes and/or embryos are validated prior to treatment being offered.

‘Other’ areas of non-compliance:

- The PR should ensure that the centre develops quality indicators for counselling and the selection and recruitment of donors
- The PR should ensure that all diagnostic testing services are provided by laboratories accredited to the appropriate standard.
- The PR should ensure that the following six SOP’s form part of the centre’s quality management system and are updated to reflect local practice at Bourn Hall Norwich: Counselling; The operation of critical equipment; Transporting of gametes and embryos; Traceability; Witnessing; Use of embryos in training.

3. The Committee noted the minutes of the last meeting, at which the Centre was granted a licence with the additional condition **‘that no licensed activity should take place at the centre until the PR provides satisfactory evidence of compliance with the outstanding recommendations relating to the major areas of non-compliance detailed in the report and referenced in paragraph 5 of these minutes’**.

4. The Committee considered the updated inspection report which contains new comments from the Executive and the Person Responsible (PR) in response to the Committee's adding of a condition to their licence.
5. The Committee noted that the lead inspector was satisfied that the Centre has addressed all of the major non-compliances within the report and recommends that the Licence Committee remove the condition from the centre's licence.
6. The Committee was unable to identify from its papers the basis on which the lead inspector had formed her view.
7. The Committee noted that the PR also gives assurances that the other areas of non-compliance will be addressed by the 13 May which is the week after the date of this meeting.

Decision

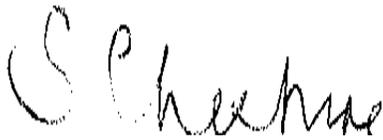
8. The Committee were not minded to remove the condition from the centre's licence at this time. They would still like either to see evidence that all of the recommendations within the original report have been fully implemented, or to understand in more detail how the lead inspector was satisfied that all major non-compliances had been addressed.
9. The Committee noted that the effect of the condition imposed was not to prevent licensed activity taking place until the condition was removed. The effect was to prevent licensed activity taking place until satisfactory evidence of compliance with major areas of non-compliance had been provided. Once that evidence had been provided the condition would be satisfied and, while it would remain on the face of the licence until removed, it would not prevent licensed activity taking place.
10. The Committee were, however, minded to amend the wording of the condition to make clear that it did not intend to reserve to itself the question of whether evidence submitted was or was not satisfactory. Mindful of the consequences of carrying out an unlicensed activity, it will also take the opportunity to make clear in the condition exactly what the effect of the condition is. The amended condition therefore reads: **'that no licensed activity should take place at the centre until the PR provides evidence that the Executive finds satisfactory of compliance with the outstanding recommendations relating to the major areas of non-compliance detailed in the report and referenced in paragraph 5 of the minutes' of the Licence Committee**

meeting of 28 March 2013. For the avoidance of doubt, once such evidence has been provided, licensed activity may take place at the centre."

11. It remains open to the PR to apply to have the licence varied to remove the additional condition, if he so wishes. If the executive has been satisfied as to compliance with major areas of non-compliance then such a variation would be essentially administrative, as licensed activity would already be permitted. If the executive has not been so satisfied then the variation would be substantive. If such an application is made then the matter should come back to the Committee. As the Committee has imposed this condition and as a variation may be substantive the Committee considers that it is correct that it should be the body to remove the condition.

Signed:

Date: 13/05/2013

A handwritten signature in black ink, appearing to read 'S Cheshire', written in a cursive style.

Sally Cheshire (Chair)