

HFEA Licence Committee Meeting

6 November 2014

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

Minutes – Item 3

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

Members of the Committee: Andy Greenfield (lay) (Chair) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Ros Foster, Browne Jacobson
Committee Secretary: Lauren Crawford	Also in Attendance: Sam Hartley, Head of Governance and Licensing
	Observing: Shelley Edwards, FieldFisher

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:

- Inspection report
- Executive Summary
- Application form
- Initial licence inspection report
- Previous licensing minutes for the last three years:
 - 28 March 2013 – initial inspection report
 - 9 May 2013 – application to remove licence condition
 - 7 June 2013 – application to change PR

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

Background

1. The Committee noted that Bourn Hall Clinic (Norwich) is a new centre in a dedicated building designed specifically for fertility patients. The centre had an initial inspection on 13 February 2013, and on 15 April 2013 the Licence Committee agreed to grant the centre's licence (L0325-1-a) for two years with an additional condition.
2. The additional condition to the licence stated;
'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'.
3. The Person Responsible (PR) submitted an application in May 2013 to remove the condition. This application also included documents to demonstrate that recommendations related to all the outstanding areas of non-compliance had been fully implemented.
4. The Licence Committee considered the application (May 2013) and were not minded to remove the condition until further evidence was provided to the Executive that compliance had been achieved and instead decided to revise the condition to read:
'That no licensed activity should take place at the centre until the PR provides evidence that the Executive finds 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 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.'

Discussion

5. The Committee noted that the Executive was satisfied that evidence had been provided that demonstrated the recommendations relating to the major areas of non-compliance were met and licensed activity has been underway since 27 May 2013.
6. The Committee noted that the centre again applied (25 June 2014) to request removal of the above condition from their licence. The application to remove the condition was initially intended to be

presented to the Licence Committee in conjunction with the renewal inspection in November 2014. However, the renewal inspection has been re-scheduled by the Executive and so this application is now being processed separately from the renewal application. The review of the evidence provided is summarised below:

- *The PR should ensure all critical procurement and processing procedures are validated prior to treatment being offered.* A complete set of validation documents covering all critical processes was submitted to the HFEA and these have been reviewed by the Executive. This evidence confirmed that all processes have been appropriately validated and meet the required standards of SLC T72.
- *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.* Detailed air quality reports from 13 August 2014 were provided to the HFEA and demonstrated that air quality has been assessed and meets all the requirements of the SLC T20.
- *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.* The centre submitted a complete list of all critical equipment as requested and the centre's inspector then selected a wide-ranging sample of validation documents for review. The clinic provided all the documents that were requested and these were reviewed by the Executive. This evidence assured the centre's inspector that all critical equipment has been validated in line with the requirements of SLC T24.

7. The Committee noted that the Executive recommends that the additional licence condition is removed from the centre's licence.

Decision

8. The Committee was satisfied, based on the application and a comprehensive range of documents submitted by the PR, that the centre has provided evidence of compliance with the Human Fertilisation and Embryology Act 1990 (as amended) in relation to section 18(2) which sets out the requirements for varying a condition(s) of a centres licence.
9. The Committee agreed to vary the centre's licence by removing the additional condition from the centre's licence.

Signed:

Date: 20 November 2014



Andy Greenfield (Chair)