

HFEA Licence Committee Meeting

19 September 2013

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

Minutes – Item 3

Centre 0049 (Wales Fertility Institute - Cardiff) – Application to Vary Licence to Remove Additional Licence Condition

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair	Lauren Crawford
Debbie Barber (professional)	
Andy Greenfield (professional)	Legal Adviser:
Gemma Hobcraft (lay)	Sarah Ellson, Field Fisher Waterhouse
	Observer:
	Sam Hartley (Head Of Governance and Licensing, HFEA)

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
- Application to lift condition
- Licence Committee (LC) / Executive Licensing Panel (ELP) minutes for three years:
 - ELP minutes 2 August 2013: Change of centre name and application
 - LC minutes 11 July: Interim inspection report
 - ELP minutes 15 March 2013: Variation of licence to change the licence holder.
 - ELP minutes 16 November 2012: Variation of licence to change the Person Responsible.
 - LC minutes 30 August 2012: Renewal inspection report of treatment and storage licence.
 - LC minutes 26 April 2012: Incident follow up inspection report.
 - Minutes of Representations hearing, 15 December 2011.
 - LC minutes 20 October 2011: Incident inspection report and accompanying documents
 - ELP minutes 24 June 2011: Variation of licence to change the Person Responsible.

- ELP minutes 20 October 2010: Variation of licence to change the Licence Holder
- ELP minutes 15 July 2010: Renewal report
- ELP minutes 24 February 2010: application for change of Licence Holder
- LC minutes 3 December 2009: breach of licence conditions
- LC minutes 10 June 2009: interim inspection report
- LC minutes 28 January 2008: incident report

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. The Licence Committee previously considered, on 20 October 2011, a 'grade B' incident which led them to impose an additional condition on the centre's licence which has remained in place. Following representations the condition states: '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 24 cycles per calendar month in total, and frozen embryo transfers to an average of eight per calendar month in total.'
2. The Committee issued the centre a two year licence in August 2012. At this time the centre did not ask for the condition to be removed and the same condition was re-imposed on the new licence.

Consideration

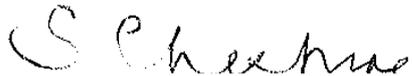
3. The Committee noted that an interim inspection was carried out on 10 April 2013. During the intervening period since the centre's current licence was granted in 2012, the centre has undergone a change of:
 - a. Person Responsible (November 2012);
 - b. Licence Holder (March 2013) and;
 - c. Senior management board (April 2013). The centre has transferred from Cardiff and Vale University Health Board to Abertawe Bro Morgannwg University Health Board (ABMU). This change was part of a restructuring of IVF services in south Wales instigated by the Welsh Health Specialised Services Committee. This centre now works in tandem with centre 0329 Wales Fertility Institute – Neath.
4. The Committee noted the minutes of the 15 December 2011 meeting where the (revised) condition was imposed and that 'limiting activity at the centre was important in order to ensure that the licensed activities at the centre were carried safely and to maintain confidence in the conduct of licensed activities at the centre'.
5. The Committee noted that the Centre has complied with the condition since it was imposed and this is reflected in the number of treatments carried out.
6. The Committee noted the PR's commitment to fully implement the remaining recommendations regarding areas of non-compliance and noted the progress the centre has made since the interim inspection was considered on 11 July 2013. It also noted the assurance given that if the licence condition were removed any increase in activity would be a staged process over which the PR would retain control.
7. The Committee noted that the Executive has no current concerns regarding the centre's overall performance and no risk-based assessment tool alerts (RBAT) have been issued regarding clinical performance. The centre continues to provide treatment in accordance with the additional licence condition and will be inspected again in 2014 before the licence is considered for renewal.
8. The Committee noted the Executive's recommendation to remove the additional licence condition and accepted the advice of its Legal Adviser that a licence could be varied to remove a condition following an application from the centre

Decision

9. The Committee urged the centre to continue to keep activity levels at the centre in-line with staffing levels to ensure issues of this nature do not arise in future.
10. The Committee asked the Executive to continue its good work with the centre by providing help and advice.
11. The Committee was satisfied with the centre's progress to date and agreed to remove the additional condition from the centre's licence with immediate effect.

Signed:

Date: 03/10/2013

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

Sally Cheshire (Chair)