

Licence Committee - minutes

Centre 0338 (Reproductive Health Group)

Item 8: Executive Update

Item 9: Change of Person Responsible

Item 10: Change of Licence Holder

Thursday, 08 November 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Andy Greenfield (Chair) Anita Bharucha Ruth Wilde Kate Brian New Authority member - Gudrun Moore (Observed for induction)	
Members of the Executive	Catherine Burwood (acting Committee Secretary) Dee Knoyle (Observer) Julie Katsaros (Observer)	Senior Governance Manager Committee Officer HFEA Inspector (induction)
Legal Adviser	Graham Miles	Blake Morgan LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

Executive update:

- Executive update
- Full paper set considered by Licence Committee on 6 September 2018 excluding minutes (provided below)
- Previous licensing minutes up to the last licence renewal inspection:
 - 6 September 2018 - executive update to Licence Committee
 - 12 July 2018 - executive update to Licence Committee
 - 3 May 2018 - executive update to Licence Committee
 - 8 March 2018 - executive update to Licence Committee
 - 11 January 2018 - interim inspection report Licence Committee
 - 7 March 2017 - variation change of Licence Holder
 - 15 January 2016 - variation change of Licence Holder
 - 15 January 2016 - renewal inspection report

Change of Person Responsible:

- Executive summary
- Application form for a change of Person Responsible
- An up-to-date CV of the proposed Person Responsible
- Email from the proposed PR stating her willingness to accept the position of Person Responsible
- Previous licensing minutes up to the last licence renewal inspection (as provided above):
 - 6 September 2018 - executive update to Licence Committee
 - 12 July 2018 - executive update to Licence Committee
 - 3 May 2018 - executive update to Licence Committee
 - 8 March 2018 - executive update to Licence Committee
 - 11 January 2018 - interim inspection report Licence Committee
 - 7 March 2017 - variation change of Licence Holder
 - 15 January 2016 - variation change of Licence Holder
 - 15 January 2016 - renewal inspection report

Change of Licence Holder:

- Executive Summary
- Application form for change of Licence Holder
- Email from the Licence Holder applicant stating that he is willing to assume responsibility of the position

Item 8: Executive update

1. Background

- 1.1. The Reproductive Health Group, centre 0338, is located in Cheshire and has held a treatment and storage licence with the HFEA since April 2014. The centre provides a full range of fertility services, including embryo testing.
- 1.2. Following an extended period of engagement with the centre since November 2017, when a routine unannounced interim inspection was carried out, the executive concluded that the PR had failed to discharge his duty under section 17(1)(d) of the Act and was no longer considered suitable to hold a licence. The PR failed to ensure that suitable practices were being used in the course of the clinic's activities and this conclusion was considered by the Licence Committee on 12 July 2018 when they considered the report of an additional inspection performed at the clinic.
- 1.3. At its meeting on 12 July 2018 the Licence Committee adjourned consideration of the report. This was to enable a meeting to take place between the Person Responsible (PR) and centre staff and the HFEA executive, as requested in submissions sent on behalf of the centre.
- 1.4. In its update to Licence Committee on 6 September 2018, the executive confirmed that the PR would be attending a meeting with the centre's inspector and the Chief Inspector on 10 September 2018.

2. Update

- 2.1. The committee noted that, at the meeting held on 10 September, the PR informed the executive that he had appointed Karen Schnauffer as Laboratory Director and that she would be making an application to become the PR of the centre. In addition, the PR explained the centre's current Licence Holder (LH) will be leaving her post and that an application to change LH would also be submitted to the HFEA.
- 2.2. Applications to vary the centre's licence to reflect the change of PR and LH were both received, and considered by the committee at this meeting also.

3. Decision

- 3.1. The committee noted the update provided and proceeded to consider the two applications submitted by centre 0338 to vary their licence to reflect a change of PR and LH.

Item 9: Change of Person Responsible

4. Consideration of application

- 4.1. The committee considered the papers, which included a completed application form and the CV of and confirmation of acceptance from the proposed new PR.
- 4.2. The committee noted that the proposed PR, Ms Karen Schnauffer, is willing to assume the responsibility of the role of PR. The committee noted that the proposed PR has satisfactorily completed the PR Entry Programme (PREP) and the certificate number was provided.
- 4.3. The committee noted that Ms Karen Schnauffer has suitable qualifications for the role of PR.
- 4.4. The committee noted from the information provided that the character, qualifications and experience of the proposed PR, Ms Karen Schnauffer, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).
- 4.5. The committee noted that all information required under General Directions 0008 had been provided.

- 4.6.** The committee noted the inspectorate's recommendation to vary the centre's licence to appoint Ms Karen Schnauffer as the PR.
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5. Decision

- 5.1.** The committee agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of PR.
- 5.2.** The committee was reassured by Ms Schnauffer's statement that she has been made aware of the compliance issues identified during the inspection in November 2017, and again in June 2018, and understands that as PR, it will be her responsibility to ensure that practice is appropriately changed to ensure compliance.
- 5.3.** The committee endorsed the inspectorate's recommendation and agreed to vary the licence of the Reproductive Health Group, centre 0338, with immediate effect to reflect the change of Person Responsible to Ms Karen Schnauffer, in accordance with Section 18A of the HFE Act 1990 (as amended).
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Item 10: Change of Licence Holder

6. Consideration of application

- 6.1.** The committee considered the papers, which included a completed application form and confirmation of acceptance from the proposed new LH.
- 6.2.** The committee noted that the proposed new LH, Dr Lee Feddy, is willing to assume the responsibility of the role of LH.
- 6.3.** The committee noted that all information required under General Directions 0008 had been provided.
- 6.4.** The committee noted the inspectorate's recommendation to vary the centre's licence to reflect the change of LH to Dr Lee Feddy.
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7. Decision

- 7.1.** The committee agreed it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of the LH.
- 7.2.** The committee endorsed the inspectorate's recommendation and agreed to vary the licence of Reproductive Health Group, centre 0338, with immediate effect, to reflect the change of Licence Holder to Dr Lee Feddy, in accordance with Section 18A of the HFE Act 1990 (as amended).
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8. Chair's signature

- 8.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Andy Greenfield

Date

3 December 2018

**Executive update for Licence Committee
8 November 2018**

Centre number	0338
Centre name	Reproductive Health Group
Person Responsible (PR)	Mr Luciano Nardo

Executive update

Background

1. At its meeting on 12 July 2018 the Licence Committee adjourned consideration of the report of an additional inspection performed at this clinic. This was to enable a meeting to take place between the PR and centre staff and the HFEA executive, as requested in the submissions on behalf of the centre. In its update to Licence Committee in September 2018, the executive confirmed that the PR would be attending a meeting with the centre's inspector and Chief Inspector on 10 September 2018.
2. The consideration by Licence Committee of activities taking place at this centre has followed an extended period of engagement with the centre since November 2017 when a routine unannounced interim inspection was carried out. Of particular concern were the following findings:
 - The executive considered that the centre's import of donor eggs from Ukraine had not been compliant with General Direction 0006 because the compensation to the egg donors was not in accordance with General Direction 0001 and that therefore the PR failed to discharge his duty. At its meeting in January 2018 the Licence Committee required the PR return the donor eggs imported in breach of General Directions 0006 and 0001, to Ukraine (completed on 1 June 2018), and to regularise the status of embryos to enable their lawful use in the UK (completed on 31 March 2018).
 - The inspection also identified a case where there were no legal parenthood consent forms in the records and the couple's treatment in 2016 had resulted in a live birth. The executive required the centre to carry out an audit of all treatments since the centre opened, and more instances where consent to legal parenthood forms were missing or incomplete were identified. An additional focussed inspection was carried out in June 2018, which identified further issues with the audit and action not being taken to deal with legal parenthood consent anomalies. On 10 July 2018 the PR informed the Executive a further anomaly in relation to consent to legal parenthood had been identified. No live birth resulted in this case.
3. The executive concluded that the PR has failed to discharge his duty under section 17(1)(d) of the Act and was no longer considered suitable to hold a licence. The PR has failed to ensure that suitable practices were being used in

the course of the clinic's activities and this recommendation was made to the Licence Committee on 12 July 2018.

Update on meeting with PR

4. The meeting with the PR was held on 10 September 2018. The PR informed the executive that he had appointed Karen Schnauffer as Laboratory Director and that she would be making an application to become the PR of the centre. Karen Schnauffer has previously been a PR at centre 0007 between 2014-2017. In addition, the PR explained the centre's current Licence Holder (LH) will be leaving her post and that an application to change LH would also be submitted to the HFEA in due course.
5. On 1 October 2018 an application for a change of PR was received by the HFEA. The Licence Committee is asked to consider that application together with this update. The proposed PR has confirmed that: 'I have been made aware of the compliance issues identified during the inspection in November 2017 and again in June 2018 and I understand that as PR it will be my responsibility to ensure that practice is appropriately changed to ensure compliance'.
6. On 5 October 2018 an application for a change of LH was received by the HFEA. The Licence Committee is asked to consider that application together with this update.

Update on progress with remaining actions

7. During the meeting with the PR on 10 September 2018 progress with the remaining actions following the inspections in November 2017 and June 2018 were also discussed, principally:
 - staffing: completing the process for the registration of relevant staff with the Health Care and Professionals Council (HCPC);
 - an audit of data submissions to HFEA, and
 - for the PR to confirm that no further issues or anomalies in consent to legal parenthood have been noted.
8. The centre has confirmed that the member of staff has completed her accreditation process and will shortly be able to apply for registration with HCPC. The centre's inspector is assured this application will be submitted within a reasonable timeframe and will review the outcome during the next inspection of the centre. **No further action is needed.**
9. An audit of data submission was provided on 10 September 2018, and in response the centre's inspector requested further clarification on the scope of the audit. On 14 September 2018 the centre's quality manager provided the raw data of the audit, and the centre's inspector noted that some issues identified in relation to consent to disclosure were not described on the audit report. Following further correspondence, on 2 October 2018 the centre's quality manager confirmed that the auditor had not recorded one finding in relation to the audit and that actions to be taken in relation to two other findings were incorporated in the general corrective actions. The executive is concerned that the centre's

inspector has identified another audit where corrective actions to be taken in response to findings have not been captured or addressed. This indicates a lack of effectiveness of the auditing process. The centre's inspector fed back these concerns to the PR and quality manager on 4 October 2018. Later that day, the quality manager provided a summary of actions taken and planned to ensure that effective processes are put in place to review the recording of audit findings. These included further staff training.

The effectiveness of the auditing process will be reviewed in detail during the next inspection at the centre.

10. On 3 October 2018, the PR confirmed that in relation to the audit of consent to legal parenthood 'There had been no issues that I have become aware since the last report.' The PR indicated that they would re-audit this area of practice in the 'new year' but in response to further correspondence he advised the centre's inspector that he will discuss this with the proposed PR and review whether an audit of recent records will be undertaken sooner than the new year.

This area of practice will be reviewed at the time of the next inspection.

Recommendations

11. The executive remains of the view that the current PR failed to discharge his duty under section 17(1)(d) of the Act and is no longer considered suitable to hold a licence. The PR has failed to ensure that suitable practices are used in the course of the clinic's activities. The executive recommends that the application to change of PR application of centre 0338 is approved.
12. The executive recommends continuation of the centre's current licence which is due to expire on 31 March 2020. The executive would usually undertake a renewal inspection approximately 6 months before the expiry of a licence, which would be in Autumn 2019. It is still the executive's intention to do so. However, given the centre's recent compliance history the executive proposes an additional inspection takes place in Spring 2019. The executive considers that this would provide the incoming PR a suitable opportunity, approximately six months, to ensure that changes and improvements in processes as a result of learning from findings during the inspections in November 2017 and June 2018 have been fully embedded into the centre's current practices.
13. The executive would expect to see robust evidence that changes, and improvements have been fully embedded into the centre's current practices and it will also enable the clinic to know what is expected of it in its inspection in Autumn 2019 for the renewal of the licence.
14. The Licence Committee is invited to consider the executive's recommendation and to make a decision in this regard.

Karen Conyers
Inspector
16 October 2018