Executive Licensing Panel - minutes

Centre 0109 (King's Fertility)

Variation of Licensed Premises

Tuesday, 12 February 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Anna Coundley Laura Riley	Director of Strategy and Corporate Affairs Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry Sandrine Oakes Nicola Lawrence	Senior Governance Manager Committee Officer (Induction) Inspector (Induction) Inspector (Induction)

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The panel noted that King's Fertility has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that in the 12 months to 30 November 2018, the centre had provided 1524 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.3. The panel noted that a renewal inspection of the centre was conducted on 11 and 12 April 2017. Recommendations were made to address one critical, seven major and six 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that all of these recommendations have been implemented.

1.4. The PR submitted a licence variation application in October 2018 to vary its licence to relocate to new premises. The new premises are located on the first floor of the Fetal Medicine Research Institute building, a short distance from the current location. The centre plans to add embryo testing to their licence, anticipating that approximately 150 patients a year will use this service. A separate application to enable this change of activities will be submitted later this year.

1.5. The panel noted that the PR plans to stop licensed activity (with the exception of storage) at the current licensed premises on 15 February 2019, with a planned closure date on 21 February 2019. The PR would like to commence treating patients at the new premises on 11 March 2019 and movement of the cryostore is planned to occur on 2 March 2019. These plans are dependent on this application being approved.

1.6. An inspection was carried out of the proposed premises on 15 January 2019 and one major area of practice requiring additional work was identified, regarding equipment. The panel noted that since the inspection, the PR has had given a commitment not use any unvalidated equipment in licensed activity.

1.7. The panel noted that should the application be approved, there will be a period of time, after the licence is varied, when the centre will still need to store gametes and embryos at the centre's 'old' premises at King's College Hospital. Therefore, a Special Direction has been requested to be in force from the date the licence is varied, for a period of three months, to allow storage of gametes and embryos at the 'old' premises until it is transferred to the new premises. The Executive considered the storage facilities at the 'old' premises to be suitable at the last inspection in April 2017, acknowledging that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the proposed Special Direction. It is recommended that the panel approves the application for a Special Direction, under delegated powers provided by Section 24, paragraph 5A, of the HF&E Act 1990 (as amended).

2. Consideration of application

2.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past three years.

2.2. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

2.3. The panel noted that the inspectorate recommends the approval of the application to vary the licence to reflect a change of premises to the following address:

King's Fertility
First Floor
Fetal Medicine Research Institute
16-20 Windsor Walk
Denmark Hill
London
SE5 8BB

2.4. The panel noted that the inspectorate recommends the approval this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable storage of gametes and embryos at the centre's 'old' premises for a period of three months after the licence is varied.

3. Decision

3.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

3.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

3.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. Subject to confirmation, from the PR, that validation has been completed on all critical equipment, the panel endorsed the inspectorate's recommendation to change the centre's licensed premises to:

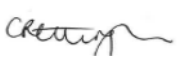
Kings Fertility
First Floor
Fetal Medicine Research Institute
16-20 Windsor Walk
Denmark Hill
London
SE5 8BB

3.5. The panel endorsed the Executive's recommendation to approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable storage of gametes and embryos at the centre's 'old' for a period of three months after the licence is varied.

4. Chair's signature

4.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

15 February 2019

Change of Premises Inspection Report

Centre name: King's Fertility
Centre number: 0109
Date licence issued: 1 October 2017
Licence expiry date: 30 September 2021
Additional conditions applied to this licence: None
Date of inspection: 15 January 2019
Inspectors: Louise Winstone and Janet Kirkland MacHattie
Date of Executive Licensing Panel: 12 February 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. Inspections are also carried out when centres apply to vary their licence to change premises. The full inspection prior to a licence being granted, renewed or varied assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of a change of premises inspection. The inspection was scheduled (rather than unannounced) and the report covers the findings from a desk-based assessment of submitted documentation, the inspection visit and communications received from the centre.

Background

King's Fertility has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

The centre provided 1,524 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2018. In relation to activity levels this is a large centre.

The centre was last inspected on 11 and 12 April 2017, when a renewal inspection was performed. Recommendations were made to address one critical, seven major and six 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that all of these recommendations have been implemented.

Following a change of ownership in 2017, the centre's licence was varied to reflect a change of centre name from King's Hewitt Fertility Centre to King's Fertility, a change of PR in October 2017 and a change of Licence Holder in November 2017.

The centre submitted an application on 24 October 2018 to vary its licence to relocate to new premises. The new premises is on the first floor of the Fetal Medicine Research

Institute building, a short distance from the current premises. The centre plans to add embryo testing to their licence, anticipating that approximately 150 patients a year will use this service. A separate application to do this will be submitted later this year.

The PR plans to stop licensed activity (with the exception of storage) at the current licensed premises on 15 February 2019, with a planned closure date on 21 February 2019. The PR would like to commence treating patients at the new premises on 11 March 2019. Movement of the cryostore is planned to occur on 2 March 2019. These plans are dependent on this application being approved.

Summary and recommendations for the Executive Licensing Panel

The Executive Licensing Panel (ELP) is asked to note that at the time of the inspection there was one area of practice that required additional work. The PR has committed to implementing the following recommendation:

Major area of non-compliance:

- The PR should ensure that any outstanding validation of new or relocated critical equipment is completed before it is used in licensed activity. The PR should ensure that the dewars and associated monitoring alarm systems are tested and validated once they have been moved to the new premises.

The Executive notes that the PR has committed to not use any unvalidated equipment in licensed activity. The Executive therefore recommends that the application to vary the licence to reflect a change of premises is approved subject to the recommendation made in this report being implemented.

The Executive notes that the new address of the centre will be:

King's Fertility
First Floor
Fetal Medicine Research Institute
16-20 Windsor Walk
Denmark Hill
London
SE5 8BB

Assuming the ELP approves this application, there will be a period of time after the licence is varied when the centre will still need to store gametes and embryos at the centre's 'old' premises at King's College Hospital. A Special Direction has therefore been requested to be in force from the date the licence is varied, for three months, to allow storage of gametes and embryos at the 'old' premises until it is transferred to the new premises. The Executive considered the storage facilities at the 'old' premises to be suitable at the last inspection in April 2017 and note that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the proposed Special Direction. It is recommended therefore that the ELP approves this application for a Special Direction, under delegated powers provided by Section 24, paragraph 5A, of the HF&E Act 1990 (as amended).

Details of Inspection findings

1. Key documents were requested from the centre in support of the change of premises application assessment, to provide assurance that the premises and equipment in the proposed new facilities are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). On completion of the desk-based assessment a site visit was conducted on 15 January 2018.

   Evidence of the following has been provided or reviewed on inspection:

   - Confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes.

- Confirmation of the building completion certification, issued by the contractor to the centre. This includes a fire safety assessment.
- Security measures in place at the new premises, including those relating to storage of gametes and embryos and confidential records were inspected during the visit and were suitable.
- Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated scanning, consulting and male production rooms are available and appear fit for purpose.
- Relevant standard operating procedures have been updated to reflect physical differences in premises.
- Patient information documents to account for the centre's address change have been prepared.
- Confirmation that a deep clean has been performed and a further deep clean is planned when all equipment has been relocated and revalidated.

2. The air cleansing and supply unit has been installed and commissioned and the results of air quality testing provide evidence that gametes and embryos will be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality.

3. A full set of new laboratory equipment sufficient to perform licensed treatment is already installed in the new laboratory. This equipment is currently being validated by an external validation company. Some existing equipment present in the old premises is to be moved to the new premises and will be re-validated prior to use (see recommendation 1).

4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in April 2017. The centre does not intend to change any activities or the type of licence as part of this application. The centre does however intend to add embryo testing to their licence at a later date.

5. The centre's cryostorage dewars will be moved to the new premises on 2 March 2019 if the licence variation application is approved, having been stored at the old premises after the licence variation under the authorisation provided by the proposed Special Direction. The dewars are to be monitored via a wireless monitoring system during transit and a risk assessment for the move has been provided. Testing and re-validation of the dewars and the monitoring and alarm system will be undertaken after re-location (see recommendation 1).

6. The PR has provided evidence that a Home Office controlled drugs licence has been approved for the new premises.

7. The centre has complied with the following requirements of General Direction 0008 (section H 14) and has supplied:
   - a relevant on-line application form;
   - a floor plan of the premises to be referenced on the licence.

8. The centre has effective plans to ensure that staff have an induction for the new premises so that they can work safely and effectively in the new workplace.

Areas of practice that require the attention of the Person Responsible

This section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non-compliance

A ‘critical’ area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified.			

‘Major’ area of non-compliance

A ‘major’ area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Equipment Validation of the new equipment in the laboratory is not yet complete. SLC T24, General Direction 0008. Testing and re-validation of the cryostorage dewars and related monitoring and alarm system cannot be undertaken until they have been transferred from the current to the new premises. SLC T24.	The PR should ensure that any outstanding validation of new or relocated critical equipment is completed before it is used in licensed activity. The PR should ensure that the dewars and associated monitoring and alarm system are tested and validated once they have been moved to the new premises. The centre’s inspector should be provided with evidence that this has been achieved before licensed treatment activity commences.	All critical equipment to be installed in the new premises has either been, or will be, validated by an external validation company. A full validation report for each equipment will be available and can be provided to the centre's inspector. No critical equipment (new or relocated) will be used for licenced actibity prior to it being validated. There is a robust plan and provisions in place to ensure that the dewars are being monitored at the new premises.The dewars and	The executive acknowledges the PR’s response and commitment to implementing the recommendation, also his assurance to not use any unvalidated equipment in licensed activity. The executive awaits confirmation that validation is complete on all critical equipment prior to commencing licensed treatment.

		associated monitoring alarm systems will be tested and validated both before the dewars relocate and again once they are in the new premises. The centre's inspector will be provided with written evidence, in the form of validation reports from the externally commisioned validation company, that the above have been achieved before licenced treatment activity commences.	

‘Other’ areas of practice that require improvement

Other areas of practice that require improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non-compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified.			

Additional information from the Person Responsible