# Human Fertilisation and Embryology Authority

## Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
**21 August 2015**

### Minutes – item no. 6

Centre 0294 (Craigavon Area Hospital) – Variation Change of Premises

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| **Members of the Panel:** | Juliet Tizzard<br>Director of Strategy & Corporate Affairs (Chair)<br>Joanne Anton<br>Policy Manager<br>Ian Peacock<br>Analyst Programmer |
| **Members of the Executive in attendance:** | Dee Knoyle<br>Committee Secretary |

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 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 the 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 Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

## Background

1. The Craigavon Area Hospital is located in Northern Ireland. The centre has held a licence with the HFEA since September 2007 and provides treatment (insemination using partner sperm). Semen analysis and preparation for insemination is performed under a third party agreement with a laboratory within the hospital's pathology department, located in another hospital building adjacent to the centre. The laboratory is unaffected by the change to the centre's premises.

2. On 12 January 2015 the PR applied to vary the licence to change the location of the licensed premises. The centre plans to relocate within the Craigavon Area Hospital to move away from the maternity and gynaecological outpatient area as concerns have been raised regarding the sensitivity of mixing infertile patients with expectant mothers.

3. The centre has currently suspended licensed activity until the variation application is approved.

## Consideration of application

4. The panel considered the papers, which included a completed variation of licensed premises application form, a floor plan of the premises to be referenced on the licence, a change of premises report and licensing minutes for the past three years.

5. The panel noted that key documents were requested from the centre in support of the change of premises application to provide assurance that the proposed new premises and equipment therein, are suitable and satisfy the legal requirements in relation to the granting of a licence. On the basis of the assessment of the submitted information and documented findings, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.

6. The panel noted that confirmation had been provided that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes.

7. The panel noted that the building work completion certificate has been issued by the building contractor.

8. The panel noted that a fire safety inspection has been performed and has confirmed the premises to be safe.

9. The panel noted that security measures at the new premises, including those relating to the security of the storage of patient records, are considered to be suitable.

10. The panel noted that privacy, comfort and confidentiality for patients have been considered in the planning of the new premises and that designated rooms for scanning, consultations, insemination procedures and semen production are available.

11. The panel noted that confirmation of an effective deep clean of clinical areas has been provided.

12. The panel noted that the centre relocated some clinical equipment from the old premises to the new and has also purchased some new equipment including an incubator, clinical refrigerator and ultrasound scanner. The PR has confirmed that new equipment has been validated and that recommissioned equipment has been tested and validated. The panel noted that the Inspectorate considers that the centre has suitable validated equipment to perform the licensed activities.

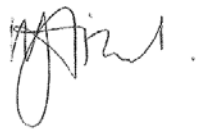
13. The panel noted that the centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in March 2012 and at the interim inspection in March 2014. The centre does not intend to change any activities or the licence type and relevant standard operating procedures and other documents in the quality management system have been updated to reflect the change in premises.

14. The panel noted that the inspectorate recommends the approval of the variation of licence application to reflect a change of premises.

**Decision**

15. The panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13).

16. The panel endorsed the inspectorate's recommendations and agreed to vary the centre's licence to reflect a change of premises to the refurbished rooms within the same hospital building as the current premises located at Craigavon Area Hospital, Lurgan Road, Portadown, Craigavon, BT63 5QQ.



Signed: Date: 24 August 2015
Juliet Tizzard (Chair)

# Change of Premises Report

**Centre name:** Craigavon Area Hospital
**Centre number:** 0294
**Date licence issued:** 01/09/2012
**Licence expiry date:** 31/08/2016
**Additional conditions applied to this licence:** None
**Date of desk-based assessment:** 10 August 2015
**Inspectors:** Andrew Leonard
**Date of Executive Licensing Panel:** 21 August 2015

## 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. The inspection prior to a licence being granted or renewed assesses a centre's compliance with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This report relates to an application for a change of premises and documents a desk-based assessment of information provided by the centre in support of the application. An onsite inspection was not required or considered necessary. The desk-based assessment reviewed the suitability of the centre's new premises against HFEA CoP and SLC requirements. The report is used to inform the HFEA Licensing Panel which will decide whether to approve the licence variation application.

## Background

This centre is located within Craigavon Area Hospital, Co. Armagh, Northern Ireland. The centre currently shares resources with the general gynaecology and maternity outpatient department.

The centre has been licensed since September 2007 and provides services for the investigation and diagnosis of subfertility and its treatment using stimulated and un-stimulated cycles of partner sperm intrauterine insemination (IUI).

Semen analysis and preparation for insemination is performed under a third party agreement with a laboratory within the hospital's pathology department, located in another hospital building adjacent to the centre. The laboratory is unaffected by the change to the centre's premises.

The last inspection of the centre was an interim inspection on 6 March 2014, during which one 'other' non-compliance were noted. Recommendations for improvement in relation to this have been fully implemented.

On 12 January 2015 the PR applied to vary the licence to change the location of the licensed premises. The centre is being relocated within Craigavon Area Hospital, away from the maternity and gynaecological outpatient area, because concerns have been raised regarding the sensitivity of mixing infertile patients with expectant mothers. The centre is to be relocated to refurbished rooms within the same hospital building as the current premises.

## Summary for the Executive Licensing Panel

The ELP is asked to note that at the time of the assessment there were no aspects of practice that required improvement.

The Executive recommends that this application to vary the licence to reflect a change of premises is approved.

The centre has currently suspended licensed activity until the variation application is approved by the HFEA. If approval is granted, the variation to the licence should be active from as soon as possible thereafter.

## Details of inspection findings

1. Key documents were requested from the centre in support of the application, to provide assurance that the premises and equipment therein, are suitable and satisfy the legal requirements in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)). On the basis of the assessment of these documents, it is concluded that the centre's proposed new premises are suitable for the conduct of licensed activities for the following reasons.
   - Confirmation has been provided that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes.
   - A building work completion certificate has been issued by the building contractor.
   - A fire safety inspection has been performed and has confirmed the premises to be safe.
   - Security measures at the new premises, described by the PR, including those relating to the security of the storage of patient records, are considered to be suitable.
   - Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated rooms for scanning, consultations, insemination procedures and semen production are available.
   - Confirmation of an effective deep clean of clinical areas has been provided.

2. The centre relocated some clinical equipment from the old premises to the new and has also purchased some new equipment including an incubator, clinical refrigerator and ultrasound scanner. The PR has confirmed that new equipment has been validated and that recommissioned equipment has been tested and validated. The inspector considers that the centre has suitable validated equipment to perform the licensed activities.

3. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in March 2012, then at the interim inspection in March 2014. The centre does not intend to change any activities or the licence type. Relevant standard operating procedures and other documents in the quality management system have been updated to reflect the change in premises.

4. The centre has complied with the requirements of General Direction 0008 (Section H 13) in submitting:
   - a relevant on-line application form;
   - a floor plan of the premises to be referenced on the licence.

## Areas of practice that require the attention of the Person Responsible

The 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 | | | |

## ‘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 |
|---|---|---|---|
| None | | | |

## ‘Other’ areas of practice that requires improvement

Areas of practice that requires 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 | | | |

| Additional information from the Person Responsible |
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