

# 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  
**22 May 2015**

### Minutes – item no. 6

Centre 0278 (Assisted Conception Unit Leigh Infirmary) – Variation of Centre name and Licensed Premises

#### Members of the Panel:

Juliet Tizzard  
Director of Strategy & Corporate Affairs (Chair)  
Joanne Anton  
Policy Manager  
Paula Robinson  
Head of Business Planning

#### Members of the Executive in attendance:

Sam Hartley  
Head of Governance & Licensing  
Dee Knoyle  
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

## Consideration of Application

1. The panel considered the papers, which included a report, a completed application form and licensing minutes for the past three years.
2. The panel noted that Assisted Conception Unit at Leigh Infirmary (centre 0278) is a small centre located in Wigan, Lancashire and has been licensed by the HFEA since 2007. The centre provides a treatment only service to patients and has recently become a secondary satellite provider for the Hewitt Fertility Centre in Liverpool (centre 0007).
3. The panel noted that the centre submitted an application on 17 March 2015 for a licence variation to change the centre name to Wrightington Wigan & Leigh Hewitt Fertility Partnership and a variation of licensed premises to improve the quality of the facilities by moving to a purpose-built unit.
4. The panel noted that the centre had submitted key documentation in support of the change of premises application 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 (HFE Act 1990 (as amended) S16 (2)(d) and (e)). The panel noted that on completion of a desk-based assessment a site visit was not required and on the basis of the evidence provided the Inspectorate concluded that the centre's proposed new premises are suitable for the conduct of treatment only licensed activities.
5. The panel noted that confirmation of the building completion certification and fire safety certification had been provided.
6. The panel noted that the centre has suitable equipment. A full set of critical laboratory equipment sufficient to perform licensed treatment is in place.
7. The panel noted that the centre's critical processes and procedures were unchanged and considered appropriate.
8. The panel noted that relevant standard operating procedures had been updated to reflect physical differences in premises.
9. The panel noted that the centre had provided the following evidence:
  - confirmation of a deep clean prior to laboratory work starting
  - air quality testing achieved the safety and quality required, grade A in the safety cabinet and grade C in the laboratory
  - validation of equipment was reviewed and considered complete.
10. The panel noted that at the time of the desk based inspection on 1 May 2015 there were no areas of non-compliance identified.
11. The panel noted the Inspectorate's recommendation for the approval of the application to vary the centre's licence to reflect a change of centre name and change of premises to:

Wrightington Wigan & Leigh Hewitt Fertility Partnership  
Wrightington Hospital  
Hall Lane, Appley Bridge  
Wigan  
Lancashire  
WN6 9EP

### **Decision**

12. The panel noted that the centre has complied with the requirements of General Directions 0008 (section H 13) in submitting a relevant application form and a floor plan of the premises to be referenced on the licence.
  
13. The panel endorsed the Inspectorate's recommendation to vary the centre's licence to reflect a change of centre name and change of premises with immediate effect.

Signed:

Date: 3 June 2015

A handwritten signature in black ink, appearing to read 'Juliet Tizzard', with a large loop at the end.

Juliet Tizzard (Chair)

# Change of Premises Report



**Centre name: Assisted Conception Unit, Leigh Infirmary**

**Centre number: 0278**

**Date licence issued: 01 July 2012**

**Licence expiry date: 30 June 2016**

**Additional conditions applied to this licence: None**

**Date of inspection: Desk based 01 May 2015**

**Inspector: Susan Jolliffe**

**Date of Executive Licensing Panel: 22 May 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. 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; this was a desk based inspection.

## Background

The Assisted Conception Unit at Leigh Infirmary is a small centre located in Wigan, Lancashire and has been licensed by the HFEA since 2007. The centre provides a treatment only service to patients, and has recently become a secondary Satellite provider for the Hewitt Fertility Centre in Liverpool.

The centre submitted an application on 17 March 2015 to vary its licensed premises to relocate to new premises, and to change the name of the centre to Wrightington Wigan & Leigh Hewitt Fertility Partnership.

The reason given for the change of premises is to improve the quality of the facilities by moving to a purpose built unit.

## 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 not required, this was agreed with the Chief

Inspector on the basis that the centre had provided a comprehensive list of documents, and the centre is treatment only.

2. On the basis of the evidence outlined below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities.
  - Confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided by the building contractor.
  - Confirmation of the building completion certification issued by the contractor to the centre was provided.
  - Confirmation of a compliant fire safety inspection was provided.
  - Security measures in place at the new premises, including those relating to confidential records, were considered to be suitable.
  - Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated counselling, scanning, consulting and male production rooms are available and fit for purpose.
  - Confirmation of a deep clean prior to laboratory work starting has been provided.
  - Air quality testing achieved the safety and quality required, grade A in the safety cabinet and grade C in the laboratory.
  - Relevant standard operating procedures have been updated to reflect physical differences in premises.
3. The centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment is in place. Validation of this equipment was reviewed and was considered complete.
4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last inspection held on 30 January 2014. The centre does not intend to change any activities or the type of licence.
5. The centre has complied with the requirements of Directions 0008 (section H 13) in submitting:
  - a relevant on-line application form;
  - a floor plan of the premises to be referenced on the licence.

### **Summary for the Executive Licensing Panel**

The ELP is asked to note that at the time of the assessment there were no areas of non-compliance.

The Executive recommends that the application to vary the licence to reflect a change of centre name and change of premises to:

Wrightington Wigan & Leigh Hewitt Fertility Partnership  
Wrightington Hospital  
Hall Lane. Appley Bridge  
Wigan. Lancashire  
WN6 9EP.