Executive Licensing Panel - minutes

Centre 0033 (Manchester Fertility) Variation of Licensed Activities to include embryo testing

Friday, 24 March 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) Howard Ryan Jessica Watkin	Head of Business Planning Report Developer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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:

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

1. Consideration of application

1.1. The panel considered the papers, which included a licence variation application report and licensing minutes for the past three years.

1.2. The panel noted that Manchester Fertility has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.3. The centre is currently on a four-year licence due to expire on 30 April 2018.

1.4. The panel noted that the centre has applied to vary its treatment and storage licence to include embryo testing.

1.5. The panel noted that an additional on-site inspection at the centre was considered unnecessary. Since the centre is scheduled to have a renewal inspection in November 2017, when a full inspection of the centre's premises and practices will be undertaken, a desk based assessment of the centre's application to vary its licence to include embryo testing was conducted.

1.6. The centre underwent an unannounced interim inspection in November 2015 and recommendations were made in relation to two critical, three major and one 'other' area of non-compliance. The inspection team recommended that an additional inspection should take place in 2016 to fully assess the continued effectiveness of corrective actions taken in response to the two critical recommendations.

1.7. The panel noted that the additional inspection took place on 29 November 2016 and all the areas of non-compliance had been resolved. The inspection found one 'other' area of non-compliance which was resolved by the centre staff prior to the report being considered by an Executive Licensing Panel on 10 February 2017, and that panel was satisfied that the treatment and storage licence for this centre should be continued.

1.8. The panel noted that the inspectorate reviewed evidence provided by the centre against the requirements of the Human Fertilisation and Embryology Act 1990 (as amended), General Directions, Standard Licence Conditions (SLCs) and the Code of Practice (CoP), with the following findings.

- **Staff** - The centre has competent staff to carry out embryo biopsy.

  The centre has submitted documented evidence of the training provided to, and the competence of, the embryologists to perform embryo biopsy (SLC T15a). Provisions are in place for patients to have access to a genetic counsellor (CoP guidance 9.1)

- **Equipment** - The centre has suitable equipment needed to carry out embryo testing. The centre has submitted documentation demonstrating that the equipment that will be used for embryo biopsy has been validated (SLC T24)

  Processes - The centre has standard operating procedures for embryo biopsy processes and the preparation and transport of biopsied samples to the testing laboratory (SLC T33b)

  The PR has confirmed genetic testing reports will not include the sex of the embryo. Information derived from tests can therefore not be used to sex select embryos for social reasons (SLC T88b).

  Quality indicators for amplification, embryo survival and clinical pregnancy rates following biopsy have been established (SLC T35).

  Evidence has been provided to demonstrate that the embryo biopsy process has been validated (SLC T72).

- **Genetic Testing** - The genetic testing will be carried out by Genesis Genetics Ltd. This laboratory has achieved Clinical Pathology Accreditation (SLC T21).

The centre has provided a third-party agreement with Genesis Genetics Ltd that is compliant with requirements (SLC T111, T112, T113 and T114).

- **Patient information** – Patient information has been submitted which provides all relevant information to meet the requirements set out in the Code of Practice (SLC T58).

1.9. The panel noted the inspectorate's recommendation to vary the centre's treatment and storage licence to include embryo testing without additional conditions.

2. Decision

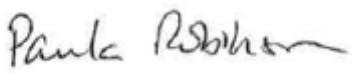
2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel endorsed the inspectorate's recommendation to vary the centre's licence to add embryo testing and thereby, to change the licence to treatment (including embryo testing) and storage, in accordance with Section 18A of the HFE Act 1990 (as amended).

3. Chair's signature

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

Signature



Name

Paula Robinson

Date

4 April 2017