Executive Licensing Panel - minutes

Centre 0196 (Jessop Fertility)

Variation of Licensed Activities to include embryo testing

Wednesday, 26 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Erin Barton	Director of Strategy & Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

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 Jessop Fertility is located in Sheffield and has held a licence with the HFEA since 2001. The centre provides a full range of fertility services.

1.3. The panel noted that, in the 12 months to 30 April 2018, the centre provided 1091 cycles of treatment (excluding partner intrauterine insemination). In relation to activity, this is a large centre.

1.4. The panel noted that, in 2017, the centre reported 317 cycles of partner insemination.

1.5. The panel noted that at the centre's last interim inspection, conducted in May 2018, recommendations were made in relation to three 'other' areas of non-compliance, which subsequently have all been addressed and at the time of writing this report, no further action was required beyond submission of audits due by August and November 2018.

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

1.7. The panel noted that the Person Responsible (PR) has confirmed that pre-implantation genetic screening (PGS) and single gene pre-implantation genetic diagnosis (PGD) will be offered to patients. The centre expects their PGS activity to be approximately 15-20 cases per year and their PGD activity to be approximately 40 cases per year.

1.8. The panel noted that at the time of the unannounced interim inspection, on 22 May 2018, the centre's premises and practices were considered suitable to recommend continuation of the centre's licence. Therefore, a further onsite visit was not considered necessary and this variation application has been reviewed as a desk-based assessment of documents provided by the centre.

1.9. The panel noted that at the time of the assessment, there were no areas of practice that required improvement.

1.10. 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 or embryo damage rates and clinical pregnancy rates following embryo 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 (GG EU) that is compliant with requirements (SLC 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).

1.11. 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

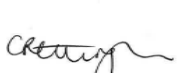
2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

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

Clare Ettinghausen

Date

5 October 2018