# Executive Licensing Panel - minutes

## Centre 0076 (NURTURE Fertility)

## Variation of Licensed Activities to include embryo testing

Wednesday, 26 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Clare Ettinghausen (Chair)<br>Dan Howard<br>Erin Barton | Director of Strategy & Corporate Affairs<br>Chief Information Officer<br>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 NURTURE Fertility is located in Nottingham and has been licensed by the HFEA since 1992. The centre is part of The Fertility Partnership group.

**1.3.** The panel noted that the centre provides a full range of fertility services and submitted an application to add embryo testing to its licence on 15 August 2018.

**1.4.** The panel noted that, at the centre's last interim inspection in March 2017, recommendations were made in relation to two major areas of non-compliance. Both recommendations were implemented within the prescribed timescales.

**1.5.** The panel noted that the Person Responsible (PR) had indicated that only pre-implantation genetic screening (PGS) will be offered. It is anticipated that approximately 20 cycles will be performed each year. The biopsies will take place at centre 0076 and a third-party laboratory will complete genetic testing of those biopsied cells.

**1.6.** The panel noted that a desk based assessment was conducted on 11 September 2018. The centre underwent an unannounced interim inspection in March 2017, which found that the centre's premises and practices were suitable such that the inspection team recommended the continuation of the centre's licence. The centre is also scheduled to have its renewal inspection in January 2019, when a further full inspection of the centre's premises and practices will be undertaken.

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

**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). Embryo testing has also been added to the centre's audit schedule (SLC T36).

  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 Cooper Genomics. This laboratory has achieved ISO 15189 Accreditation (SLC T21).

The centre has provided a third-party agreement with Cooper Genomics that it 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

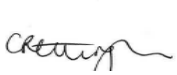
**2.1.** The panel had regard to its decision tree. It was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

**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

Clare Ettinghausen

### Date

5 October 2018