Executive Licensing Panel - minutes

Centre 0299 (CREATE Centre for Reproduction and Advanced Technology)

Variation of licensed activities to include embryo testing

Friday, 8 September 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Angeli Kara Ian Peacock	Director of Strategy and Corporate Affairs Regulatory Policy Manager Systems 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 CREATE Centre for Reproduction and Advanced Technology is located in West Wimbledon and has held a licence with the HFEA since 2008. The centre currently provides a full range of fertility services and holds a treatment and storage licence.

1.3. The panel noted there are four HFEA-licensed centres in the CREATE group, two of which already have a treatment (including embryo testing) and storage licence. There are no regulatory concerns about the embryo testing activities at these two centres. The group has a cohesive quality management system that is effectively implemented across all centres within the group.

1.4. The panel noted that the centre has applied to vary its treatment and storage licence to include embryo testing. The Person Responsible (PR) has indicated that both pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD) will be offered. Approximately 20 patients will be treated per year. The biopsies will take place at the centre and a third party laboratory will complete genetic testing of those biopsied cells.

1.5. The panel noted a desk based assessment of the application had been made and an additional on-site inspection of the centre had been considered unnecessary. The centre underwent a renewal inspection in February 2016 which found that the centre's premises and practices were suitable such that the inspection team recommended renewal of the centre's licence for a period of for years.

1.6. The panel noted that at the centre's renewal inspection in February 2016, recommendations were made in relation to two major and three 'other' areas of non-compliance; these recommendations were implemented within the required timescales.

1.7. 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 that information derived from genetic testing will not be used to select embryos of a particular sex for social reasons (SLC T88b).

  Quality indicators have been established, including embryo damage rates post biopsy (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).

1.8. 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

Juliet Tizzard

Date

12 September 2017