Executive Licensing Panel - minutes

Centre 0100 (Bourn Hall Clinic)

Variation of Licensed Activities to include embryo testing

Friday, 15 December 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Caylin Joski-Jethi Howard Ryan	Director of Strategy & Corporate Affairs Head of Intelligence Data Analyst
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 Bourn Hall Clinic is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services. The current licence has not been varied.

1.3. The panel noted that, in the 12 months to 31 August 2017, the centre provided 1879 cycles of treatment (excluding partner intrauterine insemination). In relation to activity, this is a large centre.

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 the Person Responsible (PR) had indicated that only pre-implantation genetic screening (PGS) will be offered to patients, not single gene pre-implantation genetic diagnosis (PGD). The centre expects their PGS activity to be 10 cycles per year. The centre will perform biopsy procedures relating to PGS and a third-party laboratory will complete genetic testing of those biopsied cells.

1.6. The panel noted a desk based assessment was conducted on 4 September 2017. As an interim inspection was planned for 10 October 2017, a separate on-site inspection of the centre was considered unnecessary. The interim inspection was a routine one, conducted two years after the renewal inspection in September 2015, after which the centre's licence was renewed for a period of four years with no conditions.

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 InVitro Genetics Ltd, also known as Genesis Genetics Ltd. This laboratory has achieved Clinical Pathology Accreditation (SLC T21).

  The centre has provided a third-party agreement with InVitro Genetics Ltd, also known as 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 (including embryo testing) 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

20 December 2017