Executive Licensing Panel - minutes

Centre 0314 (Leeds Fertility)

Variation of licensed activities to include embryo testing

Friday, 6 October 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Ian Peacock Anna Quinn	Director of Strategy and Corporate Affairs Systems Manager Scientific 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 Leeds Fertility has held a treatment and storage licence with the HFEA since 2010. The centre provides a full range of fertility services to NHS and privately funded patients.

1.3. The panel noted that in the 12 months to July 2017, the centre provided 2094 cycles of treatment (excluding partner intrauterine insemination) and 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. The centre currently operates as a satellite to Guys Hospital in London (centre 0102) for patients requiring PGD, which means that centre 0314 already has specialised PGD clinics and experienced genetic counsellors in place. The intention is to perform the embryo biopsy at centre 0314 and send biopsies to an accredited laboratory for DNA analysis. It is anticipated that approximately 50 extra cycles per year will be performed. The centre has applied for both PGD and PGS.

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 is scheduled to have a renewal report in May 2019, when a full inspection of their premises and practices will be undertaken.

1.6. The panel noted that at the centre's interim inspection on 23 May 2017, recommendations were made in relation to three major areas of non-compliance. The Person Responsible (PR) had addressed all of these non-compliances; two have no outstanding actions and for the third, the outcome of an audit is awaited.

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).

  Information derived from tests can therefore 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 Invitro Genetics Ltd. This laboratory has achieved Clinical Pathology Accreditation (SLC T21).

The centre has provided a third-party agreement with Invitro 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 a 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

18 October 2017