Executive Licensing Panel - minutes

Centre 0208 (CARE Tunbridge Wells) Variation of Licensed Activities to include embryo testing – Pre-implantation genetic screening (PGS)

Friday, 23 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Anna Rajakumar	Director of Strategy & Corporate Affairs Head of Regulatory Policy Scientific Policy Manager
Members of the Executive	Dee Knoyle	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 CARE Tunbridge Wells has held a licence with the HFEA since 2004. The centre provides a full range of fertility services.

1.3. The centre is currently on a four-year licence due to expire on 30 April 2018.

1.4. The panel noted that in the 12 months to 31 May 2016, the centre provided 680 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that this centre has applied to vary its treatment and storage licence to include embryo testing. The Person Responsible (PR) has confirmed that only pre-implantation genetic screening (PGS) will be offered to patients and not single gene pre-implantation genetic diagnosis (PGD). PGS investigates variations from the normal in the number of chromosomes within cells in the embryo. The centre expects its PGS activity to be 50 cycles per year.

1.6. The centre underwent an unannounced interim inspection on 3 November 2015 and at that time the premises and practices were considered suitable to recommend continuation of the centre's licence. Therefore, a further on site visit was not considered necessary and this application has been reviewed in a desk based assessment of documents provided by the centre. The panel noted that at the time of the desk based assessment on 16 July 2016 no areas of practice required improvement.

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. Biopsy procedures relating to PGS will initially be performed by specific qualified and experienced CARE team embryologists who will train relevant centre staff in the procedure.

  The centre has submitted documented evidence of the training provided to, and the competence of, the embryologists to perform embryo biopsy. The application form notes the addition of blastocyst biopsy as a training activity in which human embryos will be used.

  Equipment - the centre has suitable equipment to carry out embryo testing and arrangements have been made for the maintenance and servicing of this equipment.

  The centre has submitted documentation demonstrating that the equipment that will be used for embryo biopsy, including the Saturn laser and ICSI micromanipulation equipment, have been validated.

  Processes - The centre has standard operating procedures for embryo biopsy processes and the preparation and transport of biopsied samples to the testing laboratory.

  The PR has confirmed genetic testing reports will not include the sex of the embryo and that information derived from tests can therefore not be used to select embryos of a particular sex for social reasons.

  Quality Indicators for embryo damage rates and clinical pregnancy rates following embryo biopsy have been established.

  Evidence has been provided to demonstrate that the embryo biopsy process has been validated.

The process validation document provided by the centre includes the use of non CE marked culture media. This non-compliance was identified during the interim inspection on 3 November 2015, after which the PR agreed to implement a recommendation to address it within the agreed timescale; this deadline has yet to pass. No further recommendation is made for the purposes of this report as implementation of the recommendation will be followed up by the inspectorate as part of the ongoing monitoring of the centre's post inspection actions.

- **Genetic Testing** - the genetic testing will be carried out by Genesis Genetics Ltd (GG EU). This laboratory has achieved Clinical Pathology Accreditation.

  The centre has provided a third party agreement with GG EU that is compliant with requirements.

- **Patient information** – has been submitted and provides all relevant information to meet the requirements set out in the Code of Practice.

1.8. The panel noted the inspectorate's recommendation to vary the centre's treatment and storage licence to include embryo testing.

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 was satisfied that the requirements in the Code of Practice regarding the qualifications and training of the staff were in place to carry out pre-implantation genetic screening (PGS).

2.3. 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

5 October 2016