Executive Licensing Panel - minutes

Centre 0068 (Leicester Fertility Centre)

Variation of Licensed Activities to include embryo testing

Tuesday, 26 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Yvonne Akinmodun Laura Riley	Director of Strategy and Corporate Affairs Head of Human Resources Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing 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:

- 9th 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 Leicester Fertility Centre has held a licence with the HFEA since 1992 and provides a full range of licensed fertility treatments. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that the centre submitted an application to add embryo testing to its licence on 25 July 2019.

1.4. The panel noted that both PGT-A, also known as pre-implantation genetic screening (PGS), and PGT-M (preimplantation genetic testing for monogenic/single gene defects) will be offered by the centre. PGT-M will initially be offered to private self-funding patients. The centre is awaiting approval from their commissioning board, after which they intend to also offer PGT-M to NHS patients. It is anticipated that approximately 20 cycles will be performed each year. The biopsies will take place at centre 0068 and a third party laboratory will perform genetic testing of those biopsied cells.

1.5. The panel noted that, at the centre's last renewal inspection in June 2018, recommendations were made in relation to two major and one 'other' area of non-compliance; all recommendations were implemented within the prescribed timescales.

1.6. The panel noted that the Executive Licensing Panel (ELP) of 26 September 2018, which considered the centre's 6 August 2018 renewal report, expressed some concern in relation to a major non-compliance regarding the safety and suitability of premises. The ELP requested that an unannounced interim inspection be performed to review the actions the Person Responsible (PR) had taken to comply with the recommendations, particularly in relation to the safety and suitability of premises. The report of the unannounced inspection was considered by ELP on 12 November 2019; the panel acknowledged that all non-compliances had been fully addressed and endorsed the inspectorate's recommendation that a standard interim inspection take place at the centre in 2020, which includes a check of premises and facilities.

1.7. The panel noted a desk-based assessment was conducted on 16 October 2019 and 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 and is serviced regularly (SLC T24).

- **Processes** - The centre has standard operating procedures describing the treatment pathways for PGS and PGD, the embryo biopsy process and the preparation and transport of biopsied samples to the testing laboratory (SLC T33b). The treatment pathways and processes described are compliant with HFEA requirements.

The PR clearly stated in standard operating procedures and patient information 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 CooperSurgical and associated companies. This laboratory has achieved ISO 15189:2012 Accreditation (SLC T21) for both PGT-A (PGS) and PGT-M testing, although the testing process for PGT-M will be done in the United States, at the moment, as their laboratory in the UK is awaiting accreditation

  The centre has provided a third-party agreement with CooperSurgical, Origio and Genesis Genetics 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 (including embryo testing) and storage licence to include embryo testing without additional conditions.

2. Decision

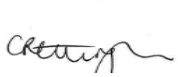
2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

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

Clare Ettinghausen

Date

4 December 2019

Licence Variation Application Report

Inspector: Mhairi West

Date of assessment: 16 October 2019

Date of Executive Licensing Panel: 26 November 2019

Purpose of report: Desk-based assessment of the centre's application to vary its licence to include embryo testing.

Centre details

Centre name	Leicester Fertility Centre
Centre number	0068
Licence number	L/0068/17/a
Centre address	Assisted Conception Unit, Women's Hospital, Leicester Royal Infirmary, Leicester, LE1 5WW, United Kingdom
Person Responsible	Jane Blower
Licence Holder	Tarek Galbaya
Date licence issued	1 October 2018
Licence expiry date	30 September 2022
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Leicester Fertility Centre has held a licence with the HFEA since 1992 and provides a full range of licensed fertility treatments. Other licensed activities at the centre include the storage of gametes and embryos.

The centre submitted an application to add embryo testing to its licence on 26 July 2019.

At the centre's last renewal inspection in June 2018, recommendations were made in relation to two major and one 'other' areas of non-compliance. All recommendations were implemented within the prescribed time scales.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre to conclude that:

- the premises are suitable for carrying out embryo testing;
- the practices are suitable for carrying out embryo testing;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licence.

The Executive Licensing Panel is asked to note that there are no areas of practice that require improvement.

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the variation of this centre's licence to include embryo testing without additional conditions.

Details of assessment findings

The licence variation application

An application has been received from the PR at centre 0068 to vary the centre's licence to add embryo testing as an additional licensed activity. Both PGT-A, also known as pre-implantation genetic screening (PGS), and PGT-M (preimplantation genetic testing for monogenic/single gene defects) will be offered by the centre. PGT-M will initially be offered to private self-funding patients. The centre is awaiting approval from their commissioning board, after which they intend to also offer PGT-M to NHS patients. It is anticipated that approximately 20 cycles will be performed each year. The biopsies will take place at centre 0068 and a third party laboratory will perform genetic testing of those biopsied cells.

The applicant has complied with all the requirements of General Direction 0008 (paragraph 6) in submitting the following:

- an application form;
- copies of information provided to patients relating to the new activity;
- evidence that the equipment and processes used in carrying out the new activity have been validated;
- a schedule of the quality indicators, and the reporting arrangements, established for this activity.

Desk-based assessment of the application

The application for a variation of the centre's licence to include embryo testing was considered using a desk based assessment.

An unrelated on-site inspection was performed at the centre on 6 August 2019. A renewal inspection in 2018 had identified a major non compliance related to the safety and suitability of the premises. The Executive Licensing Panel (ELP) of 26 September 2018 in considering the report of that inspection requested that an interim inspection be performed to review the actions the PR had taken to comply with the recommendations in the report. The inspection team considered that the PR had taken appropriate action to address the non compliances. The report of that inspection was considered by ELP on 12 November 2019. Minutes of the meeting are not yet available.

Assessment findings:

Evidence provided by the centre was reviewed 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:

A. 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).

B. Equipment

The centre has suitable equipment to carry out embryo testing. The equipment that will be used for embryo biopsy has been validated and is serviced regularly (SLC T24).

C. Processes

The centre has standard operating procedures describing the treatment pathways for PGS, the embryo biopsy process and the preparation and transport of biopsied samples to the testing laboratory (SLC T33b). The treatment pathways and processes described are compliant with HFEA requirements.

It is clearly stated in standard operating procedures and patient information 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).

D. Genetic testing

The genetic testing will be carried out by CooperSurgical and associated companies. This laboratory has achieved ISO 15189:2012 accreditation (SLC T21) for both PGT-A (PGS) and PGT-M testing, although the testing process for PGT-M will be performed in the United States at the moment as their laboratory in the UK is awaiting accreditation.

The centre has provided a third party agreement with CooperSurgical, Origio and Genesis Genetics that are compliant with requirements (SLC T111, T112, T113 and T114).

E. 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).

Areas of practice that require the attention of the Person Responsible

This section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Other areas of practice that requires improvement

Other areas of practice that require improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Additional information from the Person Responsible