Executive Licensing Panel Minutes

Centre 0336 (Simply Fertility)

Variation of Licenced Activities to include embryo testing

Date:	9 February 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Laura Riley Anna Coundley	Director of Strategy and Corporate Affairs Head of Regulatory Policy Policy Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Intelligence

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 four years.

1.2. The panel noted that Simply Fertility is situated in a purpose-built fertility clinic within Baddow Hospital in Chelmsford, Essex and initially commenced activity in August 2013 under a HFEA treatment (insemination using partner / donor sperm) and storage licence, providing a limited range of fertility treatments. The centre subsequently became a member of 'The Fertility Partnership' group, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a full treatment and storage licence.

1.3. The panel noted that the centre submitted an application to add embryo testing to its licence on 11 December 2020.

1.4. The panel noted that the Person Responsible (PR) had stated that the centre wishes to provide PGT-A, also known as pre-implantation genetic screening (PGS), and PGT-M (preimplantation genetic testing for monogenic/single gene defects) services at the centre. The PR anticipates that approximately two to five treatment cycles, involving embryo testing, will be performed each month. Embryo biopsies will be conducted at centre 0336 and a third party laboratory will perform genetic testing of those biopsied cells.

1.5. The panel noted that the centre's renewal inspection was conducted in June 2019 and recommendations were made in relation to three major and one 'other' area of non-compliance. All of the recommendations were implemented within the prescribed timescales and the centre's licence was renewed for four years.

1.6. The panel noted that, in March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). The HFEA suspended all inspections until 1 November 2020. A revised inspection methodology was subsequently adopted to take into consideration UK measures to contain and mitigate the spread of the virus. These methods enable compliance to be reviewed through desk based assessment (DBA) of documents submitted by the centre as well as the use of virtual technology where available and appropriate. A risk based approach (RBA) is then applied, balancing the risks of on-site inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

1.7. The panel noted that a desk-based assessment, for this variation of activities application, was conducted on 21 January 2021 and no items of concern were identified, so an on-site inspection has not been necessary. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.8. The panel noted that 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 embryologist to perform embryo biopsy (SLC T12).

Provisions are in place for patients to have access to a genetic counsellor (CoP guidance 9.1).

Training documents were also provided to support the future training of another embryologist (SLC T12). Contingency plans have also been developed in case the biopsy practitioner is unexpectedly sick.

Equipment - The centre has suitable equipment needed to carry out embryo testing. 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 pathways for treatments involving embryo testing, for the embryo biopsy process and for 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 CooperGenomics and associated companies. This laboratory has achieved ISO 15189:2012 Accreditation (SLC T21) for both PGT-A (PGS) and PGT-M testing,

The centre has provided a third-party agreement with CooperGenomics 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 that the inspectorate recommendation to vary the centre's treatment and storage licence to include embryo testing, without additional conditions.

2. Decision

2.1. The panel had regards 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. Chairs signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Clare Ettinghausen

Date

15 February 2021

Licence Variation Application Report

Inspector: Andrew Leonard

Date of assessment: 21 January 2021

Date of Executive Licensing Panel: 9 February 2021

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

Centre details

Centre name	Simply Fertility
Centre number	0336
Licence number	L/0336/3/b
Centre address	Baddow Hospital, West Hanningfield Road, Great Baddow, Chelmsford, CM2 8HN, United Kingdom
Person Responsible (PR)	Sarah Glew
Licence Holder	Laurel Hird
Date licence issued	27 November 2019
Licence expiry date	26 November 2023
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history

Simply Fertility is situated in a purpose-built fertility clinic within Baddow Hospital in Chelmsford, Essex.

Simply Fertility initially commenced activity in August 2013 under a HFEA 'Treatment (Insemination using partner / donor sperm) and Storage' licence, providing a limited range of fertility treatments. The centre subsequently became a member of 'The Fertility Partnership' group, upgraded the clinical and laboratory facilities and varied their licence in May 2017 to a full 'Treatment and Storage' licence.

At the centre's last renewal inspection in June 2019, recommendations were made in relation to three major and one 'other' areas of non compliance. All recommendations were implemented within the prescribed timescales and the centre's licence was renewed for four years. The centre provides a full range of fertility services including the storage of gametes and embryos.

The centre submitted an application to vary its licence to include embryo testing on 11 December 2020.

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 for centre 0336 to vary the centre's licence to add 'embryo testing' as an additional licensed activity. Specifically the application form records as 'current activities' all activities for which the centre is already licensed, and notes as proposed activities: PGD, PGS and Polar body biopsy. The PR has advised that the centre wishes to provide PGT-A, also known as pre-implantation genetic screening (PGS), and PGT-M (preimplantation genetic testing for monogenic/single gene defects) services at the centre.

The PR anticipates that approximately two to five treatment cycles involving embryo testing will be performed each month. Embryo biopsies will take place at centre 0336 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

In March 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). The HFEA suspended all inspections until 1 November 2020. A revised inspection methodology was subsequently adopted to take into consideration UK measures to contain and mitigate the spread of the virus.

These methods enable compliance to be reviewed through desk based assessment (DBA) of documents submitted by the centre as well as the use of virtual technology where available and appropriate. A risk based approach (RBA) is then applied, balancing the risks of on site inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

For this variation of the licensed activities at centre 0336 to include embryo testing, the DBA/RBA concluded no items of concern were identified so on site inspection has not necessary. This removed the risks to patient and all staff concerned, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

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 embryologist to perform embryo biopsy (SLC T12). Provisions are in place for patients to have access to a genetic counsellor (CoP guidance 9.1). Training documents were also provided to support the future training of another embryologist (SLC T12). Contingency plans have also been developed in case the biopsy practitioner is unexpectedly sick.

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 pathways for treatments involving embryo testing, for the embryo biopsy process and for 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 rate 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 CooperGenomics and associated companies. This laboratory has achieved ISO 15189:2012 accreditation (SLC T21) for both PGT-A and PGT-M testing.

The centre has provided a third party agreement with CooperGenomics that is 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