# Executive Licensing Panel Minutes

## CARE Woking (0144)

## Variation of Licenced Activities to include embryo testing

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| Date: | 13 July 2021 | |
| Venue: | HFEA Teleconference Meeting | |
| Attendees: | Clare Ettinghausen (Chair)<br>Kathleen Sarsfield-Watson<br>Niamh Marren | Director of Strategy and Corporate Affairs<br>Communications Manager<br>Regulatory Policy Manager |
| Executive: | Bernice Ash | Secretary |
| 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 CARE Woking (formerly Nuffield Health Assisted Conception Services) is located in Surrey and has held a licence with the HFEA since 1994. In October 2020, the centre became part of the CARE group of fertility centres, changing its name to CARE Woking. The centre is in the process of embedding the practices and processes of the CARE group of clinics.

**1.3.** The panel noted that the centre submitted an application to add embryo testing to its licence on 27 April 2021.

**1.4.** The panel noted that the Person Responsible (PR) had stated that the centre will undertake PGT-A, also known as pre-implantation genetic screening (PGS). The PR has confirmed that the centre only intends to perform PGT-A and will not perform PGT-M (preimplantation genetic testing for monogenic/single gene defects, also known as preimplantation genetic diagnosis (PGD)). It is anticipated that approximately 50 cycles will be performed each year. This estimate differs to that initially given to the HFEA as documented in the application form of 100 patients per year. Embryo biopsies will take place at this centre and a third party laboratory will perform genetic testing of the biopsied cells.

**1.5.** The panel noted that the centre's interim inspection was conducted in March 2021 and recommendations were made in relation two major areas of non-compliances concerning the Quality Management System (QMS) and medicines management. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendation surrounding medicines management and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance regarding the QMS. The Executive Licensing Panel (ELP) was satisfied the centre was fit to have its treatment and storage licence continued.

**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 onsite inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

**1.7.** The panel noted that a DBA was conducted, between 13 May and 21 June 2021. At the time of the assessment, no items of concern were identified, so an on-site inspection was not required. This removed the risk to patients and all staff concerned, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

**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 PGT-A and PGT-M, 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 CooperGenomics, a Cooper Surgical company. This laboratory has achieved ISO 15189:2012 Accreditation (SLC T21) for PGT-A (PGS) 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 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, thereby changing it to a treatment (including embryo testing) and storage licence, 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

19 July 2021

# Licence Variation Application Report

**Inspector:** Karen Conyers and Karen Campbell

**Date of assessment:** 13 May to 21 June 2021

**Date of Executive Licensing Panel:** 13 July 2021

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

## Centre details

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| **Centre name** | CARE Woking |
| **Centre number** | 0144 |
| **Licence number** | L0144-14-f |
| **Centre address** | 5 Hillview Road, Woking, Surrey, GU22 7HW |
| **Person Responsible** | Mr Andrew Riddle |
| **Licence Holder** | CARE Fertility Group Limited |
| **Date licence issued** | 1 October 2019 |
| **Licence expiry date** | 30 September 2023 |
| **Additional conditions applied to this licence** | None |

# Contents

# Report to Executive Licensing Panel

## Brief description of the centre and its licensing history:

CARE Woking (formerly Nuffield Health Assisted Conception) is located in Surrey and has held a licence with the HFEA since 1994. In October 2020 the centre became part of the CARE group of fertility centres and the centre changed its name to CARE Woking. The centre is in the process of embedding the practices and processes of the CARE group of clinics.

The centre provides a full range of fertility services. Other activities include the storage of gametes and embryos. At the centre's last interim inspection in March 2021, there were two major areas of non compliance identified concerning the quality management system (QMS) and medicines management. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendation surrounding medicines management and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance regarding the QMS. The executive licensing panel (ELP) was satisfied the centre was fit to have its treatment and storage licence continued. The centre submitted an application to add embryo testing to its licence on 27 April 2021.

The current licence has been varied to reflect the following changes;

- 4 March 2021 – all centres: variation of all licences without application (European Union (EU) Exit requirements.
- 29 October 2019 – variation change of premises and change of centre name.
- 9 January 2020 – change of Licence Holder (LH).
- 5 November 2020 – change of LH and change of centre name.

## 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 0144 to vary the centre's licence to add embryo testing as an additional licensed activity. If approved, the centre will undertake PGT-A, also known as pre-implantation genetic screening (PGS). The PR has confirmed that the centre only intends to perform PGT-A and will not perform PGT-M (preimplantation genetic testing for monogenic/single gene defects, also known as preimplantation genetic diagnosis (PGD)). It is anticipated that approximately 50 cycles will be performed each year. This estimate differs to that initially given to us as documented in the application form of 100 patients per year. Embryo biopsies will take place at centre 0144 and a third party laboratory will perform genetic testing of the 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 0144 to include embryo testing, the DBA/RBA concluded no items of concern were identified so an on site inspection was not necessary. This removed the risks to patients 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 embryologists to perform embryo biopsy (SLC T15a). Patients 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 embryo testing, 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 CooperGenomics, a Cooper Surgical company. This laboratory has achieved ISO 15189:2012 accreditation (SLC T21) for PGT-A (PGS).

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