# Executive Licensing Panel - minutes

## Centre 0299 (CREATE Centre for Reproductive and Advanced Technology) Renewal Inspection Report

Friday, 20 May 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

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| Panel members | Juliet Tizzard (Chair)<br>Howard Ryan<br>Anjeli Kara | Director of Strategy & Corporate Affairs<br>Technical Report Developer<br>Regulatory Policy Manager |
| Members of the Executive | Dee Knoyle<br>Ian Brown | Secretary<br>Head of Corporate Governance |
| 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 completed application form, inspection report, executive update and licensing minutes for the last three years.

**1.2.** The panel noted that CREATE Centre for Reproduction and Advanced Technology (centre 0299) is located in West Wimbledon, London. The centre provides a full range of fertility services. In relation to activity levels this is a medium-sized centre.

**1.3.** The panel noted that the centre has been licensed by the HFEA since 2008.

**1.4.** The panel noted that in the 12 months to 31 December 2015, the centre provided 571 cycles of treatment (excluding partner intrauterine insemination).

**1.5.** The panel noted that for IVF and ICSI, HFEA-held register data for the year ending September 2015 showed the centre's success rates were in line with national averages.

**1.6.** The panel noted that in 2015 the centre reported 13 cycles of partner insemination with two clinical pregnancies. The national average for this year is not currently available.

**1.7.** Between October 2014 and September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 14%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target for this period.

**1.8.** The panel noted that at the time of the renewal inspection on 9 and 10 February 2016, two major and three other areas of non-compliance were identified. The panel noted that since the inspection all of the recommendations to address the non-compliances have been implemented and the PR will provide evidence of further audit to demonstrate the effectiveness of the corrective action taken by 10 August 2016.

**1.9.** The panel noted that some improvement is required in order for the centre to demonstrate the suitability of its practices. The centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

**1.10.** The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

## 2. Decision

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

**2.2.** The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

**2.3.** The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge her duty under section 17 of the HFE Act 1990 (as amended).

**2.4.** The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

## 3. Chair's signature

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

### Signature

### Name

Juliet Tizzard

### Date

3 June 2016

**Executive Update for Executive Licensing Panel 20 May 2016**

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| **Centre number** | 0299 |
| **Centre name** | CREATE Centre for Reproduction and Advanced Technology |
| **Person Responsible** | Geeta Nargund |

**Update to renewal inspection report**

## Background

1. Centre 0299's renewal application is being considered by this Executive Licensing Panel (ELP).

2. The report of the renewal inspection of centre 0299 made five recommendations for improvement. Four of these recommendations were due to be completed, or had elements that were due to be completed by 10 May 2016.

3. Annex 1 provides an update on the implementation of these four recommendations.

4. All recommendations have now been implemented. The PR will provide evidence of further audit to demonstrate the effectiveness of the corrective action taken by 10 August 2016.

**Sara Parlett**
**Inspector**

## Annex 1: Recommendations that required further action

Note: Only recommendations that were due to be implemented by 10 May 2016 have been included in the list below. The original numbering for non-compliances from the inspection report has been retained.

### Critical area of non compliance

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

### Major area of non compliance

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| 1. **Surrogacy**<br>The records of a recent surrogacy case performed at the centre were reviewed. The inspection team was concerned that both the surrogate and the commissioning couple thought that the intended father would be the legal parent from birth, when this may not be the case because the surrogate is married and her partner's lack of consent to treatment had not been | The PR should conduct a review of the centre's procedures for providing surrogacy treatment to ensure that appropriate information is given and effective consent to legal parenthood is obtained. This review should include staff training requirements and a root cause analysis of the issues noted in the case reviewed on inspection.<br><br>The outcome of the review | Whilst the surrogate did not complete a LC form, her husband did complete a SWC 'Surrogacy - Withdrawing Your Consent' form which clarified his intention in relation to legal parenthood. We will ensure that the LC form is used in such circumstances henceforth.<br>A full review will be conducted as requested and the outcome of the review and an action plan will be | The inspection team acknowledges the PR's response and commitment to fully implement this recommendation.<br><br>The PR will be providing the outcome of the review of legal parenthood in surrogacy arrangements to the centre's inspector by 10 May 2016.<br><br>**Update 10 May 2016:** The PR has provided a copy of |

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| clearly established.<br><br>The inspection team considers that this omission may be indicative of a lack of understanding at the centre of legal parenthood consent requirements for surrogacy.<br><br>CoP Interpretation of mandatory requirements 6G. | and an action plan with timescales for the implementation of any changes should be provided to the centre's inspector by 10 May 2016. | provided to the centre's inspector by 10 May 2016. In-Depth Training has already been delivered last month to all staff regarding consenting patients for Surrogacy and Legal Parenthood. This will be an on-going programme as part of our multi-disciplinary team meetings and training sessions. | the review of the centre's surrogacy procedures. This includes details of corrective actions taken, for example conducting a consent workshop for all staff involved in obtaining consent to legal parenthood in surrogacy arrangements.<br><br>No further action required. |
| 2. **Consent to disclosure**<br>Four discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted to the register. Two of these discrepancies presented a risk that the HFEA may release patient identifying information, to researchers, without consent. In these cases, the patients had returned to the centre for further treatment and had changed their disclosure consent, but this change had | The PR has corrected the four submissions that were identified as incorrect.<br><br>The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. This should include any variations to consent previously given by patients. | Our EDI compliance manager has confirmed that all six corrections have already been sent. She also confirms that although six out of 16 were identified as discrepancies, this figure should have been four out of 16 as corrections for two patients had been previously submitted (before the inspection).<br><br>We have reviewed the procedures for checking and submitting consent to disclosures and further | The inspection team acknowledges the PR's commitment to fully implement this recommendation.<br><br>The inspection team acknowledges that two corrections were made prior to inspection and the report has been amended accordingly.<br><br>**Update 10 May 2016:** The PR has provided a copy of the centre's comprehensive review which includes details |

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| not been submitted to the HFEA.<br><br>General Direction 0005.<br><br>It is noted that contact research would not be initiated by the HFEA and it would be expected that if the clinic was asked to initiate contact research, consent forms would be reviewed before patients are contacted.<br><br>**This was an issue at the previous inspection.** | A summary of the findings and any corrective actions identified should be submitted to the centre's inspector by 10 May 2016.<br><br>Three months after the implementation of corrective action, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 10 August 2016.<br><br>It is also recommended that the clinic undertakes a further representative retrospective sample audit of relevant records (i.e. where consent to non contact research has been withdrawn upon return to the centre). The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in these | internal training for staff will be delivered by our compliance lead to outline this.<br>A full review will be conducted and summary of findings and corrective actions will be submitted to the centre's inspector by 10 May 2016. Further specific audits will be undertaken and findings will be submitted by 10 August 2016<br>An additional EDI administrator currently being recruited will be responsible for the monthly auditing of consent to disclosure.<br>We will liaise with the HFEA's register team as recommended. | of actions taken in response to the review findings.<br><br>A retrospective sample audit of 75 sets of notes has also been conducted. This found three errors, none of which presented a risk that the HFEA may release patient identifying information to researchers without consent.<br><br>A summary report of the audit to determine the effectiveness of this corrective action to be submitted to the centre's inspector by 10 August 2016. |

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| | circumstances.<br><br>The PR should advise the HFEA of the findings of this audit by 10 August 2016.<br><br>On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit. | | |

## Other areas of practice that requires improvement

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| 3. **Medicines management**<br>The centre does not consistently record the disposal of an unused portion of a controlled drug accurately in the register.<br><br>SLC T2; Safer management of controlled drugs – a guide | The PR should identify corrective actions to ensure that the disposal of unused portions of controlled drugs is always recorded in the register. The PR should provide a summary of these actions identified when responding to this report. | As witnessed by the inspection team, the correct and compliant systems were in place but some anaesthetists had not recorded the amount disposed in the controlled drug book. This has now been addressed with all | The inspection team acknowledges the PR's response and the corrective action that has been implemented.<br><br>The PR will be performing an audit to ensure that these corrective actions have been |

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| to good practice 4.16.1.2. | An audit to assess that the corrective actions are effective should take place in May 2016 and a summary of the audit should be provided to the centre's inspector. | anaesthetists and a new column has been introduced in the controlled drug book to record disposal of any unused drug since the inspection. It is now fully addressed and the PR can confirm it. An audit and summary will be provided to the centre's inspector in May 2016 | effective and will be providing a copy of this audit to the centre's inspector in May 2016.<br><br>**Update 10 May 2016:** The PR has provided the summary of an audit performed demonstrating that disposal of unused portions of controlled drugs are recorded in the register.<br><br>No further action required. |
| 5. **Data Submission**<br>Eleven percent of the IVF and fourteen percent of the DI treatments had been reported to the HFEA outside the period required.<br><br>At the time of inspection, HFEA records showed that four unregistered donors had been used in treatment.<br><br>General Direction 0005.<br><br>**This was an issue at the previous inspection.** | The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.<br><br>The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for poor quality submissions. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective | The PR will ensure that all licensed treatment activity is reported within the timeframe required.<br>The Centre is only aware of one treatment with an unregistered donor. The donor should have been registered by another UK Centre as this is where the donor sperm was sourced from. We were informed by that Centre that the Donor was registered.<br>We have requested that Centre to submit the registration for this donor. | The inspection team acknowledges the PR's commitment to fully implement this recommendation.<br><br>It is also acknowledged that the term 'unregistered' with respect to the three other donors is inaccurate. These donors had been registered, but had been registered incorrectly. The recommendation remains the same.<br><br>**Update 10 May 2016:** The |

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| | actions should be submitted to the centre's inspector by 10 May 2016.<br><br>Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 10 August 2016. | We are not aware of any other unregistered donors. This was discussed with the EDI inspector.<br>A full review will be conducted and a report will be submitted to the centre's inspector by 10 May 2016. A further review and audit will then be undertaken after 3 months. | PR has provided a copy of the summary of the review of procedures for data submission, including the corrective action to be implemented.<br><br>A summary report of the audit to determine the effectiveness of this corrective action to be submitted to the centre's inspector by 10 August 2016. |

# Inspection Report

## Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

**Date of inspection:** 9 and 10 February 2016

**Purpose of inspection:** Renewal of a licence to carry out Treatment with Storage

**Inspection details:** The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

**Inspectors:** Sara Parlett (Lead), Susan Jolliffe, David Gibbon, Neil McComb

**Date of Executive Licensing Panel:** 20 May 2016

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| **Centre name** | CREATE Centre for Reproduction and Advanced Technology |
| **Centre number** | 0299 |
| **Licence number** | L/0299/3/a |
| **Centre address** | 3-5 Pepys Road, West Wimbledon, SW20 8NJ |
| **Person Responsible** | Geeta Nargund |
| **Licence Holder** | Stuart Campbell |
| **Date licence issued** | 1 August 2012 |
| **Licence expiry date** | 31 July 2016 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

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

CREATE Centre for Reproduction and Advanced Technology is located in West Wimbledon and has held a treatment and storage licence with the HFEA since 2008.

The centre provides a full range of fertility services and provided 571 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2015. In relation to activity levels this is a medium size centre.

Other licensed activities of the centre include storage of gametes and embryos.

### Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending September 2015 show the centre's success rates are in line with national averages.

In 2015 the centre reported 13 cycles of partner insemination with two clinical pregnancies. The national average for this year has not yet been calculated.

### Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between October 2014 and September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

## Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that there were a number of areas of practice that required improvement, including two major and three 'other' areas of non compliance.

Since the inspection visit, the centre has provided evidence that the following recommendations have been fully implemented:

'Other' areas that require improvement:

- The PR should ensure that the disposal of unused portions of controlled drugs is recorded in the controlled drugs register.
- The PR should ensure that their third party agreement (TPA) with the diagnostic laboratory covers all relevant requirements.

The PR has given a commitment to fully implement the following recommendations within the prescribed timescales:

Major areas of non compliance:

- The PR should conduct a review of the centre's procedures for providing surrogacy treatment to ensure that appropriate information is given and effective consent to legal parenthood is obtained.
- The PR should review procedures and take appropriate corrective actions to ensure that disclosure consent decisions supplied to the Authority accurately reflect those given and recorded by patients on disclosure consent forms.

'Other' areas that require improvement:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

## Recommendation to the Executive Licensing Panel

The centre has two major of areas of concern. The inspection team notes that the success rates are consistent with the national average and the centre's multiple clinical pregnancy rate is likely to meet the live birth rate target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

# Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

## 1. Protection of the patient and children born following treatment

### Witnessing and assuring patient and donor identification

**What the centre does well**

**Witnessing (Guidance note 18)**
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

**What the centre could do better**
Nothing identified at this inspection.

### Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

**What the centre does well**

**Screening of donors (Guidance note 11)**
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos.

**Payments for donors (Guidance note 13; General Direction 0001)**
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

**Donor assisted conception (Guidance note 20)**
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to

access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

**What the centre could do better**
Nothing identified at this inspection.

## Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

**What the centre does well**

**Safety and suitability of premises and facilities (Guidance note 25)**
The centre's premises are suitable, with one exception described below. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

**Laboratory accreditation (Guidance note 25)**
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or

any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control**
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management**
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

**Pre-operative assessment and the surgical pathway**
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

**Multiple births (Guidance note 7; General Direction 0003)**
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

**Procurement of gametes and embryos (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- if sperm is procured at home, keep a record of this in the gamete provider's records.

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

**Receipt of gametes and embryos (Guidance note15)**

The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and have enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

**Imports and exports (Guidance note 16; General Direction 0006)**
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

**Traceability (Guidance note 19)**
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

**Quality management system (QMS) (Guidance note 23)**
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

**Third party agreements (Guidance note 24)**
The centre's third party agreements are broadly compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

**Equipment and materials (Guidance note 26)**
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

**Process validation (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

**Adverse incidents (Guidance note 27)**
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events

and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

**What the centre could do better**

**Safety and suitability of premises and facilities (Guidance note 25)**
The flooring in the cryostore is cracked and requires replacement. This has been noted by centre staff and it will be replaced during the next routine laboratory shut-down to ensure any volatile organic compounds used during the renovation do not impact on embryo development. The inspection team considers this to be an appropriate approach and that a recommendation is not required.

**Medicines management**
The centre does not consistently record the disposal of an unused portion of a controlled drug in the register. Three recent entries showed a part ampoule was given, this was recorded accurately in the three patient records, but the controlled drug register did not have a record of the remainder of the ampoule being disposed of.

The inspection team is confident from talking to staff and observing practice that this is a record keeping issue, and the system for witnessing the disposal of any unused controlled drug is performed correctly (Safer management of controlled drugs – a guide to good practice 4.16.1.2, recommendation 3).

**Third party agreements (Guidance note 24)**
The centre's TPA with the diagnostic laboratory performing virology testing does not document how test results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. In July 2014 the HFEA also recommended that such TPAs specify the third parties responsibilities to inform the centre if the testing laboratory adapts protocols for CE approved tests or if it receives a performance alert from UK NEQAS. These points are not covered in the centre's TPA (SLC T114f, recommendation 4).

## Staff engaged in licensed activity
**Person Responsible (PR)**
**Staff**

**What the centre does well**

**Person Responsible (Guidance note 1)**
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1143/7).

**Staff (Guidance note 2)**
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The

centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

**What the centre could do better**
Nothing identified at this inspection.

## Welfare of the child and safeguarding

**What the centre does well**

**Welfare of the child (Guidance note 8)**
The centre's procedures to ensure that the centre takes into account, before treatment is provided, the welfare of any child who may be born as a result of the licensed treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

**Safeguarding**
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

**What the centre could do better**
Nothing identified at this inspection.

## Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

**What the centre does well**
The centre does not perform embryo testing and therefore this area of practice is not applicable to this inspection.

**What the centre could do better**
Not applicable to this inspection.

## 2. The experience of patients

### Patient feedback

**What the centre does well**

During the inspection visit the inspectors spoke to five patients who provided positive feedback on their experiences. A further ten patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was mostly positive, with seven of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

The centre's own patient satisfaction survey results were discussed on inspection. The results of these surveys are carefully considered, demonstrating a learning culture at the centre. Corrective actions are taken to address any negative trends in patient feedback.

**What the centre could do better**

Nothing identified at this inspection.

### Treating patients fairly

**Counselling**
**Egg sharing arrangements**
**Surrogacy**
**Complaints**
**Confidentiality and privacy**

**What the centre does well**

**Treating patients fairly (Guidance note 29)**

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

**Counselling (Guidance note 3)**

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

**Egg sharing arrangements (Guidance note 12; General Direction 0001)**
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

**Surrogacy (Guidance note 14)**
The centre's procedures for treatment involving surrogacy are partially compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

**Complaints (Guidance note 28)**
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

**Confidentiality and privacy (Guidance note 30)**
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

**What the centre could do better**

**Surrogacy (Guidance note 14)**
If a surrogate is married at the time of embryo transfer, her partner will be the legal parent of any child born as a result of her treatment (and will have parental responsibility), unless it is shown that s/he did not consent to the embryo transfer. For these purposes, lack of consent requires a basis in fact. Parenthood in these circumstances can be complex and case specific, and for the family court or births registrar (or both) to decide.

The records of a recent surrogacy case performed at the centre were reviewed. The surrogate is married and her husband had initially consented to be the legal parent on an internal consent form, but then subsequently withdrew this consent. The intended father (and gamete provider) completed the HFEA's SPP consent form, consenting to be the legal parent, and the surrogate completed the HFEA's SWP consent form, nominating the intended father as the legal parent. The inspection team was concerned that the surrogate and the commissioning couple thought that the intended father would be the legal parent from birth, when this may not be the case because the surrogate is married and clear lack of consent, including (but not limited to) completion of the HFEA form 'LC stating spouse's lack of consent' was not established (Interpretation of mandatory requirements 6G; recommendation 1). The inspection team considers that this omission may be indicative of a lack of understanding of legal parenthood consent requirements for surrogacy at the centre. It is noted that this treatment was unfortunately unsuccessful and therefore there is no impact to any legal parenthood issues in this case.

## Information

**What the centre does well**

**Information (Guidance note 4; Chair's Letter CH(11)02)**
The centre's procedures for providing information to patients and donors are compliant. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

**What the centre could do better**
Nothing identified at this inspection.

## Consent
## Legal Parenthood, and
## Disclosure of information, held on the HFEA Register, for use in research

**What the centre does well**

**Consent (Guidance note 5)**
The centre's procedures for obtaining consent are compliant with HFEA requirements, with the exception of consent relevant to legal parenthood in surrogacy cases as discussed elsewhere in this report. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

**Legal parenthood (Guidance note 6)**
Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided evidence that their audit was comprehensive and that their procedures for obtaining consent to parenthood are robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed three sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The centre's procedures are compliant with legal parenthood requirements.

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases patient identifying information, to researchers, with consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

**What the centre could do better**

**Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)**
Four discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. Two of these discrepancies presented a risk that the HFEA may release patient identifying information, to researchers, without consent. In these cases, the patients had returned to the centre for further treatment and had changed their consent, but this change had not been submitted to the HFEA (General Direction 0005, recommendation 2).

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman; and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

**What the centre could do better**

Nothing identified at this inspection.

### Screening of patients
### Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 17)**

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos.

**Storage of gametes and embryos (Guidance note 17)**

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

**What the centre could do better**

Nothing identified at this inspection.

| **Use of embryos for training staff** (Guidance note 22) |
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| **What the centre does well**<br><br>**Use of embryos for training staff (Guidance note 22)**<br>The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority. |
| **What the centre could do better**<br>Nothing identified at this inspection. |

## 4. Information management

**Record keeping**
**Obligations and reporting requirements**

What the centre does well

**Record keeping and document control (Guidance note 31)**
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained, with one exception detailed in the medicines management section of this report. Good medical records are essential for the continuity of the patient's care.

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

**What the centre could do better**

**Obligations and reporting requirements (Guidance note 32; General Direction 0005)**
Eleven percent (13/121) of the IVF and fourteen percent (3/22) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.

At the time of inspection, HFEA records showed that four unregistered donors had been used in treatment. The Authority attaches great importance to resolving apparently unregistered donors because of the potential adverse impact they could have on the HFEA's ability to fulfil statutory obligations to donors and the donor conceived (General Direction 0005; recommendation 5).

# Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to four areas of major non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented, with the exception of the following two, where non compliances were noted again at this inspection:

- The PR should ensure that consent to disclosure of identifying information to re-searchers is submitted accurately to the HFEA (recommendation 2).

- The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframes required (recommendation 5).

## On-going monitoring of centre success rates

The centre has not received any success rate risk tool alerts in the last two years.

## Areas of practice requiring action

The 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, General Direction 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, or a significant shortcoming from the statutory requirements. 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 |
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| 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 |
|---|---|---|---|
| 1. **Surrogacy**<br>The records of a recent surrogacy case performed at the centre were reviewed. The inspection team was concerned that both the surrogate and the commissioning couple thought that the intended father would be the legal parent from birth, when this may not be the case because the surrogate is married and her partner's lack of consent to treatment had not been clearly established.<br><br>The inspection team considers that this omission may be indicative of a lack of understanding at the centre of | The PR should conduct a review of the centre's procedures for providing surrogacy treatment to ensure that appropriate information is given and effective consent to legal parenthood is obtained. This review should include staff training requirements and a root cause analysis of the issues noted in the case reviewed on inspection.<br><br>The outcome of the review and an action plan with timescales for the implementation of any changes should be provided to the centre's inspector by 10 May 2016. | Whilst the surrogate did not complete a LC form, her husband did complete a SWC 'Surrogacy - Withdrawing Your Consent' form which clarified his intention in relation to legal parenthood. We will ensure that the LC form is used in such circumstances henceforth.<br>A full review will be conducted as requested and the outcome of the review and an action plan will be provided to the centre's inspector by 10 May 2016.<br>In-Depth Training has already been delivered last month to all staff regarding consenting patients for Surrogacy and Legal Parenthood. This will be an on-going programme as part | The inspection team acknowledges the PR's response and commitment to fully implement this recommendation.<br><br>The PR will be providing the outcome of the review of legal parenthood in surrogacy arrangements to the centre's inspector by 10 May 2016. |

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| legal parenthood consent requirements for surrogacy.<br><br>CoP Interpretation of mandatory requirements 6G. | | of our multi-disciplinary team meetings and training sessions. | |
| 2. **Consent to disclosure**<br>Four discrepancies were found between 16 completed patient/partner disclosure consents on patient files and the related consent data submitted to the register. Two of these discrepancies presented a risk that the HFEA may release patient identifying information, to researchers, without consent. In these cases, the patients had returned to the centre for further treatment and had changed their disclosure consent, but this change had not been submitted to the HFEA.<br><br>General Direction 0005.<br><br>It is noted that contact research would not be initiated by the HFEA and it would be expected that if the clinic was | The PR has corrected the four submissions that were identified as incorrect.<br><br>The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. This should include any variations to consent previously given by patients.<br><br>A summary of the findings and any corrective actions identified should be submitted to the centre's inspector by 10 May 2016.<br><br>Three months after the implementation of corrective action, the centre should perform an audit to ensure that these corrective actions have | Our EDI compliance manager has confirmed that all six corrections have already been sent. She also confirms that although six out of 16 were identified as discrepancies, this figure should have been four out of 16 as corrections for two patients had been previously submitted (before the inspection).<br><br>We have reviewed the procedures for checking and submitting consent to disclosures and further internal training for staff will be delivered by our compliance lead to outline this.<br>A full review will be conducted and summary of findings and corrective actions will be submitted to the centre's inspector by 10 May 2016.<br>Further specific audits will be undertaken and findings will be | The inspection team acknowledges the PR's commitment to fully implement this recommendation.<br><br>The inspection team acknowledges that two corrections were made prior to inspection and the report has been amended accordingly. |

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| asked to initiate contact research, consent forms would be reviewed before patients are contacted.<br><br>**This was an issue at the previous inspection.** | been effective. This audit should be submitted by 10 August 2016.<br><br>It is also recommended that the clinic undertakes a further representative retrospective sample audit of relevant records (i.e. where consent to non contact research has been withdrawn upon return to the centre). The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in these circumstances.<br><br>The PR should advise the HFEA of the findings of this audit by 10 August 2016.<br><br>On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit. | submitted by 10 August 2016<br>An additional EDI administrator currently being recruited will be responsible for the monthly auditing of consent to disclosure.<br>We will liaise with the HFEA's register team as recommended. | |

## Other areas of practice that requires improvement

Areas of practice that requires 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 |
|---|---|---|---|
| 3. **Medicines management**<br>The centre does not consistently record the disposal of an unused portion of a controlled drug accurately in the register.<br><br>SLC T2; Safer management of controlled drugs – a guide to good practice 4.16.1.2. | The PR should identify corrective actions to ensure that the disposal of unused portions of controlled drugs is always recorded in the register. The PR should provide a summary of these actions identified when responding to this report.<br><br>An audit to assess that the corrective actions are effective should take place in May 2016 and a summary of the audit should be provided to the centre's inspector. | As witnessed by the inspection team, the correct and compliant systems were in place but some anaesthetists had not recorded the amount disposed in the controlled drug book. This has now been addressed with all anaesthetists and a new column has been introduced in the controlled drug book to record disposal of any unused drug since the inspection. It is now fully addressed and the PR can confirm it. An audit and summary will be provided to the centre's inspector in May 2016 | The inspection team acknowledges the PR's response and the corrective action that has been implemented.<br><br>The PR will be performing an audit to ensure that these corrective actions have been effective and will be providing a copy of this audit to the centre's inspector in May 2016. |
| 4. **TPAs**<br>The centre's TPA with the diagnostic laboratory performing virology testing does not document how test results are relayed to the centre, including sign off and | A suitably revised TPA was submitted to the HFEA soon after the inspection visit.<br><br>No further action is required. | N/A | N/A |

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| confirmation that the result applies to the correct sample.<br><br>The HFEA recommended to the sector in July 2014 that such TPAs should also include informing the centre if the testing laboratory adapts protocols for CE approved tests or if it receives a performance alert from UK NEQAS. These points are not covered in the TPA.<br><br>SLC T114f. | | | |
| 5. **Data Submission**<br>Eleven percent of the IVF and fourteen percent of the DI treatments had been reported to the HFEA outside the period required.<br><br>At the time of inspection, HFEA records showed that four unregistered donors had been used in treatment.<br><br>General Direction 0005.<br><br>**This was an issue at the previous inspection.** | The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.<br><br>The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for poor quality submissions. A summary report of the findings of the review including corrective actions and the timescale for implementation of corrective actions should be | The PR will ensure that all licensed treatment activity is reported within the timeframe required.<br>The Centre is only aware of one treatment with an unregistered donor. The donor should have been registered by another UK Centre as this is where the donor sperm was sourced from. We were informed by that Centre that the Donor was registered. We have requested that Centre to submit the registration for this donor. | The inspection team acknowledges the PR's commitment to fully implement this recommendation.<br><br>It is also acknowledged that the term 'unregistered' with respect to the three other donors is inaccurate. These donors had been registered, but had been registered incorrectly. The recommendation remains the same. |

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| | submitted to the centre's inspector by 10 May 2016.<br><br>Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 10 August 2016. | We are not aware of any other unregistered donors.<br>This was discussed with the EDI inspector.<br>A full review will be conducted and a report will be submitted to the centre's inspector by 10 May 2016.<br>A further review and audit will then be undertaken after 3 months. | |

| Response from the Person Responsible to this inspection report |
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| The Person Responsible and staff at Create Fertility Wimbledon are grateful to the inspection team for their time and advice during the inspection. We found the inspection team very thorough, open-minded and constructive. It was a time to exchange our experiences and thoughts in order to continue with an excellent service to our patients. We are also grateful to our patients who provided a positive feedback to the inspection team about the care received at our centre.<br>We are very proud to offer safer, successful, individualised and physiological methods of IVF to our patients. We have not had a single woman admitted to hospital with Ovarian Hyperstimulation Syndrome (OHSS). We are providing an "OHSS Free" IVF service for many years with modern stimulation protocols. Create Fertility is committed to reducing cost and increasing safety and accessibility in IVF. |