

Executive Licensing Panel - minutes

Centre 0359 (CREATE Fertility Manchester) Initial Inspection Report - Treatment (with embryo testing) & Storage Licence

Friday, 2 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) David Moysen Trisram Dawahoo	Director of Strategy and Corporate Affairs Head of IT Digital Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. CREATE Fertility Manchester is located at:

King's Court
Water Lane
Wilmslow
Cheshire
SK9 5AR

1.2. The proposed Person Responsible (PR), Mr Paul Wilson, submitted an application for a new treatment (including embryo testing) and storage licence in February 2017.

1.3. The centre will operate as part of the CREATE corporate group that includes three other HFEA licensed centres: CREATE Fertility Birmingham (centre 0348), CREATE, St Paul's London (centre 0339) and CREATE Centre for Reproduction and Advanced Technology (centre 0299). The group has a cohesive quality management system that is effectively implemented across all centres within the group. The other three clinics have been inspected within the last 15 months and any recommendations for improvement have been implemented. Therefore, the desk-based assessment and on-site inspection focussed on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

1.4. The desk based assessment was performed first, followed by an inspection on 17 May 2017.

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report, CV of the proposed Person Responsible (PR) and confirmation of acceptance of the role from the proposed Licence Holder (LH).

2.2. The panel noted the findings of the desk-based assessment and inspection carried out on 17 May 2017.

2.3. The panel noted that the proposed PR, Mr Paul Wilson, has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme and already holds this position at CREATE Fertility Birmingham (centre 0348).

2.4. The panel noted the suitability of the proposed LH, Mr Praful Nargund.

2.5. The panel noted the suitability of the premises for the conduct of licensed activities.

2.6. The panel noted that at the time of the inspection on 17 May 2017, there were two major and two 'other' areas of practice that required improvement. The major areas of non-compliance concerned fire safety and equipment validation. The 'other' areas of non-compliance related to infection control and PGS patient information. The panel noted that since the inspection, the PR has fully implemented the non-compliances regarding PGS patient information and fire safety. The PR has committed to implementing the remaining recommendations prior to starting licensed activities.

2.7. The panel noted that the inspectorate considered that there is sufficient information available to recommend:

- the appointment of the proposed PR;
- the appointment of the proposed LH;

- the grant of a treatment (including embryo testing) and storage licence for a period of two years, with no additional conditions.

3. Decision

- 3.1.** The panel referred to its decision tree.
- 3.2.** The panel was satisfied that the appropriate application form was submitted.
- 3.3.** The panel noted that the inspectorate had received the supporting information required by General Directions 0008 and was satisfied that the fee had been paid.
- 3.4.** The panel was satisfied that the proposed PR, Mr Paul Wilson, will discharge his duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Mr Paul Wilson as the Person Responsible when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).
- 3.5.** The panel was satisfied with the suitability of the proposed LH, Mr Praful Nargund. The panel agreed to appoint Mr Praful Nargund as the Licence Holder when the new licence comes into effect.
- 3.6.** The panel was satisfied that the premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.
- 3.7.** The panel was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.
- 3.8.** The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.
- 3.9.** The panel agreed to grant the licence for treatment (including embryo testing) and storage for a period of two years with no additional conditions.
- 3.10.** The panel noted the inspectorate's reasons not to conduct an interim inspection. However, the panel felt that even though CREATE Fertility Manchester is part of a wider group of clinics, with good levels of compliance, the inspectorate should conduct an interim inspection, within a year, to check the centre is operating as expected.

4. Chair's signature

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

Signature



Name

Juliet Tizzard

Date

13 June 2017

Initial Licence Report



Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. 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: 17 May 2017

Purpose of inspection: Review of an application for a treatment (including embryo testing) and storage licence

Inspection details: The report covers the findings from a desk based assessment of submitted documentation, the inspection visit and communications received from the centre.

Inspectors: Sara Parlett and Gill Walsh.

Date of Executive Licensing Panel: 2 June 2017

Centre name	CREATE Fertility Manchester
Centre number	0359
Centre address	King's Court Water Lane Wilmslow Cheshire SK9 5AR
Proposed Person Responsible	Mr Paul Wilson
Proposed Licence Holder	Mr Praful Nargund

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Section 1: Summary report

Brief description of the centre:

CREATE Fertility Manchester is a new private fertility treatment centre. The proposed Person Responsible (PR) has applied for a treatment (including embryo testing) and storage licence to allow provision of a full range of fertility services.

The centre will operate as part of the CREATE corporate group that includes three other HFEA licensed centres: CREATE Fertility Birmingham (0348), CREATE, St Paul's London (0339) and CREATE Centre for Reproduction and Advanced Technology (0299). The group has a cohesive quality management system that is effectively implemented across all centres within the group. The other three clinics have been inspected within the last 15 months and any recommendations for improvement have been implemented. Taking this into consideration, this desk based assessment and on-site inspection has focussed on local compliance with group policies and procedures, as well as the compliance of the centre's premises and facilities.

The proposed PR and proposed Licence Holder (LH) already hold these positions at centre 0348.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	1500
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination (IUI)	500
Pre-implantation Genetic Diagnosis/Screening (PGD/S)	100
Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

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 been submitted by the individual designated to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- subject to the PR implementing the recommendations made in this report, it is considered likely the PR will discharge his duties under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable, subject to the confirmation of fire safety;
- the centre's proposed practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for an initial licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were two major and two 'other' areas of practice that require improvement.

Since the inspection visit, a recommendation to address the following non compliance has been fully implemented:

'Other' areas that require improvement:

- The PR should revise the centre's PGS patient information to make it clear that further studies are needed to assess whether PGS significantly increases live birth rates.

The PR has committed to implementing the following recommendation before the ELP considers this application:

Major area of non compliance:

- The PR should ensure that a fire safety risk assessment has been performed for the centre.

The PR has committed to implementing the following recommendations prior to starting licensed activities:

Major area of non compliance:

- The PR should ensure that the cryo-storage dewars and dry shipper are validated.

'Other' areas that require improvement:

- The PR should ensure that bacteriological assessment of relevant areas is performed to ensure their suitability.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Person Responsible;
- the appointment of the proposed Licence Holder;
- the grant of a treatment (including embryo testing) and storage licence for a period of two years, as is standard for an initial licence, with no additional conditions: subject to the implementation of the recommendations in this report.

As this centre is part of an established corporate group which collectively demonstrates a good level of compliance, the inspection team does not consider that the standard approach of conducting an interim inspection within the first year is indicated in this instance.

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 proposed 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 proposed 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 proposed 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 proposed 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 although the final assessment of fire safety is outstanding. This is important to ensure that all licensed activities are conducted in an appropriate environment that is fit for purpose.

The centre's proposed procedures 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 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 will 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 (Guidance note 25)

The centre's proposed systems to manage and monitor the prevention and control of infection are compliant with guidance. However, microbiological testing of relevant areas of the premises to confirm this has not yet been carried out.

Medicines management (Guidance note 25)

The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicine are compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not intend offering intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance note 25)

The centre's proposed policies and procedures 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 proposed 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 proposed 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;
- where the sperm is procured at home, the centre proposes to 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 proposed procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes and embryos sent to other licensed centres within or outside the UK are:

- 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;
- shipped in a container/package which is validated, properly secured and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note 15)

The centre's proposed 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 they are appropriately labelled and have enough accompanying 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 proposed procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)

The centre's proposed 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,
- 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 compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)

The centre does not intend to establish transport and satellite arrangements.

Equipment and materials (Guidance note 26)

The centre proposes to use equipment and materials that are compliant with HFEA requirements. All of the equipment and materials to be used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is broadly 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 proposed 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 proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report adverse incidents (including serious adverse

events and reactions) to the HFEA and will investigate all incidents that occur. 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)

Notwithstanding that the inspection team considers all necessary fire preventative measures, signage and procedures are in place, a final fire risk assessment by an independent expert has been scheduled but not yet performed (SLC T17; recommendation 1).

Infection control (Guidance note 25)

The clinical and laboratory areas have not yet been tested for microbiological cleanliness. The PR advised that now all equipment has been installed and all but the dewars validated, a further deep clean is planned for the week following the inspection, after which microbiological testing will be performed (SLC T17; recommendation 3).

Equipment and materials (Guidance note 26)

Liquid nitrogen will not be delivered until the centre is closer to being licensed by the HFEA. The PR has confirmed that the centre's dewars and the dry shipper can only be fully validated once delivery has taken place (SLC T24; recommendation 2).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)

The proposed PR has complied with HFEA requirements during the application process and in preparing the centre for licensed activity.

The proposed PR has academic qualifications in the field of biological sciences 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/1288/82). The PR is also currently PR at CREATE Fertility, Birmingham (0348). The PR has given appropriate assurances to the inspection team that both PR roles can be covered sufficiently. The proposed PR described that staffing and resources will be monitored to ensure they are commensurate with the activities to be provided to ensure an effective and safe service.

Staff (Guidance note 2)

The centre is compliant with HFEA requirements. The centre has 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 proposed procedures to ensure that they take 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 proposed 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

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)

The centre's proposed procedures for performing embryo testing are compliant with HFEA requirements, with one exception. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information and opportunities to discuss the implications of their treatment, and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better

The inspection team considers that the centre's patient information regarding PGS does not make it as clear as it should, that more robust clinical and laboratory trials are needed to assess whether or not PGS significantly increases live birth rates (CoP Guidance 9.3).

2. The experience of patients

▶ Patient feedback

What the centre does well

The centre has developed effective systems to seek patient feedback and has provided assurance that this feedback will be reviewed regularly and, where necessary, actions will be taken to address problems in the service communicated via patient feedback.

On the basis of discussions with centre staff and a review of documents in the course of the inspection it was possible to assess that the centre:

- will have respect for the privacy and confidentiality of patients in the clinic;
- will give patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- will provide patients with satisfactory facilities for their care;
- will have a mechanism in place to effectively respond to patient calls and queries in a timely manner.

What the centre could do better

Nothing identified at this inspection.

▶ Treating patients fairly

Counselling

Egg [and sperm] sharing arrangements

Surrogacy

Complaints

Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)

The centre's proposed 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 or sperm provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)

The centre's proposed procedures for treatment involving surrogacy are 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 proposed 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

Nothing identified at this inspection.



Information

What the centre does well

Information (Guidance note 4; CH(11)02)

The centre's proposed procedures for providing information to patients and donors are compliant with HFEA requirements, with one minor exception noted in the 'Embryo testing' section of this report. 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 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 proposed procedures for obtaining consent are compliant with HFEA requirements. 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 is 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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre's proposed procedures for collecting legal parenthood consent are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

The centre's proposed procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

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

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes and embryos

▶ Respect for the special status of the embryo

What the centre does well

The centre's proposed 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 proposed 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 proposed 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 will only store 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)

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre's proposed 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

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 proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. 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 proposed procedures for submitting information about licensed activities to the Authority are 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

Nothing identified at this inspection.

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 Directions or the Code of Practice, and the recommended improvement actions 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	PR Response	Executive Review
None identified on this inspection.			

▶ **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 represent a major area of non-compliance.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
<p>1. Fire safety</p> <p>A fire risk assessment by an independent expert has been scheduled but not yet performed (SLC T17).</p>	<p>The PR should provide the centre's inspector with a copy of the fire risk assessment confirming the premises are safe, prior to this report being considered by a licensing committee and before the centre opens to the public.</p>	<p>The final fire inspection is scheduled on 22nd May at 8 AM. The certificate will be sent prior to the ELP meeting .</p>	<p>The Executive acknowledges the PR's response.</p> <p>An update will be provided to the ELP prior to their meeting.</p>
<p>2. Equipment validation</p> <p>The dewars and the dry shipper, have not yet been validated (SLC T24).</p> <p>The PR has confirmed that the validations will be completed once liquid nitrogen delivery has taken place.</p>	<p>The PR should provide the centre's inspector with a copy of the validation documents for the dewars and dry shipper prior to commencing licensed activity.</p>	<p>The validations will be completed and documents will be sent prior to commencing licensed activities</p>	<p>The Executive acknowledges the PR's response and awaits the validation documents prior to licensed activities commencing.</p>

► **‘Other’ areas of practice that require improvement**

An ‘other’ area 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 constitutes a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review
<p>3. Infection control</p> <p>The clinical and laboratory areas have not yet been tested for microbiological cleanliness (SLC T17).</p> <p>Microbiological testing is planned after a further deep clean and before licensed activities commence.</p>	<p>The PR should provide the centre’s inspector with a copy of the summary of the microbiological testing results confirming the premises are suitably clean, prior to commencing licensed activity.</p>	<p>The PR will provide a copy of the summary of the microbiological testing results confirming that the premises are suitably clean prior to the ELP meeting if possible.</p>	<p>The Executive acknowledges the PR’s response and awaits receipt of the documentation prior to licensed activities commencing.</p>
<p>4. PGS patient information</p> <p>The inspection team considered that the centre’s patient information for PGS should make it clearer that more robust clinical and laboratory trials are needed to assess whether or not PGS significantly increases live birth rates (CoP Guidance 9.3).</p>	<p>The PR has committed to reviewing and revising the PGS patient information.</p> <p>The PR should provide the centre’s inspector with a copy of the revised information sheet when responding to this report.</p>	<p>A revised patient information sheet is attached.</p>	<p>The revised patient information sheets have been provided.</p> <p>No further action is required.</p>

Further response from the Person Responsible to this inspection report

The PR and staff of Create Fertility Manchester are grateful to the inspection team for their time and thorough inspection. We always appreciate the guidance from the inspection team and the HFEA in general for their support. We are committed to delivering the most cost-effective and the best care to our patients. Create Fertility takes pride in reducing complications, preventing OHSS and providing less invasive and successful treatment options to women and couples .