Executive Licensing Panel - minutes

Centre 0335 (In-OVO Fertility Clinic)

Initial Inspection Report – Treatment and Storage Licence

Tuesday, 14 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Anna Coundley	Director of Strategy and Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. In-OVO Fertility Clinic is located at:

Unit 1 Portside Business Park
189 Airport Road West
Belfast
County Antrim
BT3 9ED

1.2. The proposed Person Responsible (PR), Dr Efstathios Diakos, submitted an application for a treatment and storage licence in June 2019 to allow for the provision of a full range of fertility services as well as the storage of oocytes, sperm and embryos.

1.3. In-OVO Fertility Clinic is a private centre located in Belfast. The centre occupies a two story unit in an office block and the premises having been recently refurbished to ensure it is suitable for licensed activity.

1.4. A desk based assessment was performed, followed by an inspection on 28 November 2019.

2. Consideration of application

2.1. The panel considered the papers which included an application form, inspection report and CV of the proposed Person Responsible (PR).

2.2. The panel noted the findings of the desk based assessment alongside the inspection carried out on 28 November 2019.

2.3. The panel noted that at the time of the inspection, there were four major areas of non-compliance regarding the safety and suitability of premises, the Quality Management System (QMS), equipment and materials and counselling. Since the inspection visit, the PR has provided evidence that actions have been taken to implement all the recommendations before licensed treatment commences.

2.4. The panel noted that the proposed PR, Dr Efstathios Diakos, 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.

2.5. The panel noted the suitability of the proposed Licence Holder (LH), Mr Rory Powe.

2.6. The panel noted the suitability of the premises for the conduct of 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 and storage licence for a period of two years, subject to the implementation of the recommendations made in the report.

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, Dr Efstathios Diakos, will discharge his duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Dr Efstathios Diakos 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 Rory Powe. The panel agreed to appoint Mr Rory Powe as the Licence Holder when the new licence comes into effect.

3.6. The panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on the 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.

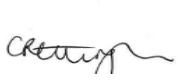
3.8. The panel referred to 'guidance on periods for which new or renewed licences can be granted' which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

3.1. The panel agreed to grant the licence for treatment and storage for a period of two years with no additional conditions, subject to all the recommendations made in the report being fully addressed, welcoming the receipt of the interim report in 2021. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

20 January 2020

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: 28 November 2019

Purpose of inspection: Review of an application for a treatment 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: Mhairi West & Polly Todd

Date of ELP: 14 January 2020

Centre name	In-OVO
Centre number	0335
Centre address	Unit 1 Portside Business Park 189 Airport Road West BELFAST BT3 9ED
Proposed Person Responsible	Dr Efstathios Diakos
Proposed Licence Holder	Rory Powe

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Section 1: Summary report

Brief description of the centre:
In-Ovo is a private centre located in Belfast. The centre occupies a two story unit in an office block, the centre's premises having been recently refurbished to ensure it is suitable for licensed activity.

The proposed Person Responsible (PR) has applied for a HFEA treatment and storage licence. The centre will provide a full range of fertility services as well as the storage of oocytes, sperm and embryos.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	360
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination IUI	120
Pre-implantation genetic diagnosis / screening (PGD/S)	N/A

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 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 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 four areas of practice which required additional work.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations before licensed treatment commences:

Major areas requiring improvement:

- the PR should ensure that actions required are taken to make the premises suitable;
- the PR should ensure that all staff working in the centre are up to date with current legislation and regulatory guidance, ensure that safeguarding processes are in place to protect patients and staff from harm where possible and ensure that there are documented processes in place for all activities, including clinical and non-clinical emergencies;
- the PR should ensure that a complete set of critical equipment is validated;
- the PR should provide the centre's inspector with the requested information regarding processes for implications counselling.

Recommendation to ELP

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

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the granting of a Treatment and Storage licence for a period of two years subject to the implementation of the recommendations in this report. An interim inspection will be completed during the first year as a useful indication of early performance and progress.

Centre 0335 has not applied for an Importing Tissue Establishment (ITE) import certificate, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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, with the proviso described in recommendation 2. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or 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

Screening of donors (Guidance note 11)
The centre has not taken into account the recent changes to donor screening guidelines when developing their process.

SLC T53, United Kingdom Guidelines for the Medical and Laboratory Procurement and Use of Sperm Egg and Embryo Donors, 2019; see recommendation 2.

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 partially suitable. This is important to ensure that all licensed activities are conducted in an appropriate environment that is fit for purpose.

The centre has not yet performed final health and safety assessments to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre has not yet performed final air quality testing to demonstrate compliance with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The 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 to be accreditation by UKAS, the national accreditation body for the UK, or another accreditation body recognised as 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.

Medicines management (Guidance note 25)
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are compliant with guidance.

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe 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 note15)
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.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre does not propose to import gametes or embryos from TCSs outside the EU/EEA and has not applied for an ITE import certificate. The centre's proposed procedures are therefore compliant with General Direction 0006.

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 partially 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 have any transport and satellite activities and therefore this area of inspection is not applicable at this centre.

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 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 partially 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)
The inspection team considers that the premises will be suitable once the following matters have been addressed:

- the final certification confirming fire, and health and safety risk assessments are not yet available;
- safety signage, including for fire prevention and liquid nitrogen, is not yet in place.
- building security, including alarms and CCTV, is not yet installed.

There are various areas throughout the centre where the space between the floor and the wall is not sufficiently sealed for clinical areas.

The clinical and laboratory areas have not yet been tested for microbiological cleanliness and air quality. A further deep clean is planned following the inspection visit once equipment has been installed, after which microbiological and air quality testing will be performed.

The call bell system in the recovery area does not include an emergency call, distinct from the general alert signal, and there is not an emergency call bell in the men's production room.

The audible low oxygen alert alarm only sounds outside the laboratory, on the bottom floor of the centre. This would not be heard on the upper floor and, as the staff complement is small, there is a high possibility that no one would hear it. There is no planned training for all staff in the management of medical gases, or how to respond in the event of a liquid nitrogen burn or a low oxygen alarm in the building.

Emergency services have not been informed that the centre is a healthcare facility with medical gases and liquid nitrogen on site.

SLC T17 and T20; see recommendation 1.

Quality management system (QMS) (Guidance note 23)
The PR and the clinic/quality manager have not worked under UK regulation or guidelines since 2013 and have not signed up to receive Clinic Focus emails. The inspection team is not satisfied that a system is in place to ensure that the centre's processes are up-to-date with regulatory guidance issued in Clinic Focus articles and recent updates to the Code of Practice, in particular guidance related to consent to legal parenthood, and screening guidelines for donors.

The centre has not established safeguarding processes and the identified lead has not had training at the appropriate level.

SLC T12, CoP 25.33, 25.35 and 25.36.

The centre does not have a documented procedure to follow in the event of clinical and non clinical emergencies, including lack of clinical cover, and does not have a business continuity agreement with another licenced centre, in the event that they cannot provide licensed treatment, including storage.

SLC T10.

The centre does not have documented processes to cover;

- management of storage of gametes and embryos,
- patient support,
- updated guidelines related to donor screening,
- consideration of patient and donor travel history.

SLC T33, T53, see recommendation 2.

Equipment and materials (Guidance note 26)
Equipment is in the process of being installed and commissioned. Some validation documentation has been supplied to the centre's inspector but there are still some items outstanding, including the equipment monitoring system, and cryostore alarms and monitoring.

SLC T24; see recommendation 3.

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 medicine and 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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good

governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Staff (Guidance note 2)
The centre is partially 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

Staff (Guidance note 2)
On the day of inspection there was a nominated registered medical practitioner, a lead nurse and an HCPC-registered embryologist on site. This would be sufficient staff for the small numbers of patients that the centre intend to treat initially. However the inspection team was concerned that a contingency plan had not been considered for the event that one of these members of staff was not able to attend work. The inspection team acknowledges that the centre is currently implementing a recruitment program for nurses and embryologists. The PR is the sole nominated medical practitioner so contingency arrangements in the event that he is unavailable are especially important.

See recommendation 2.

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 partially 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

Safeguarding
The centre does not have a documented safeguarding SOP, and there is not a lead member of staff trained to the appropriate level.

SLC T12, CoP 25.33, 25.35 and 25.36.; see recommendation 2.

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 will not perform embryo testing and therefore the requirements surrounding this were not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

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.

Patient support (Guidance note 3)

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's proposed patient support procedures are partially compliant with HFEA guidance.

SLC T33, T53; see recommendation 2.

Counselling (Guidance note 3)
The centre's proposed counselling procedures are partially 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.

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 provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre does not intend to offer surrogacy treatments and therefore this area of inspection is not applicable to this centre.

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

Counselling (Guidance note 3)
The centre's arrangements for counselling were assessed by an external examiner.

The documented processes for implications counselling, for all forms of third party family creation/donation, are not sufficiently detailed.

SLC T59; T60 and T61; see recommendation 4.

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. 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;6)
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 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.

The centre's proposed processes for collecting legal parenthood consent at this centre 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/or 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 will not use embryos for training staff therefore this area of inspection is not applicable to this centre.
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 ; 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			

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
1. Suitability and Safety of Premises Evidence of final building fire safety assessment, and of a final health and safety risk assessment is still required. Safety signage, including medical gas and liquid nitrogen storage, is not yet in place. The clinical and laboratory areas have not yet been tested for microbiological cleanliness and air quality. A further deep clean is planned once equipment has been fully installed, after which microbiological and air quality testing will be performed. There are various areas throughout the centre where the	The PR should ensure that actions required are taken to make the premises suitable, and should provide the centre's inspector with: • a copy of the fire risk assessment; • a copy of the health and safety risk assessment; • confirmation that appropriate safety signage and building security measures have been installed and commissioned, where necessary. The PR should provide a summary of the microbiological and air quality testing results, confirming the premises are suitably clean and that processing of gametes/embryos will take place in an environment that complies with the air quality requirements of SLC T20. This must	A Fire Risk assessment took place on the 20th November and a certificate of conformity was issued. New fire extinguishers and signage were installed around the building on the 22nd November (copies attached). CCTV, Fire alarm and intruder alarm systems are installed and commissioned and monitoring is provided via a monitoring station(copies of certificates are attached). A Health & Safety risk assessment will take place w/c 06/01 when all furniture and medical equipment is installed and in place and a copy of the	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required, other than submission of evidence of health and safety risk assessment, air quality testing and confirmation of signage installation.

area between the floor and the wall is not sufficiently sealed for clinical areas. The call bell system in the recovery area does not include an emergency call, distinct from the general alert signal, and there is not an emergency call bell in the men's production room. The audible low oxygen alert alarm only sounds on the bottom floor of the centre. This would not be heard on the upper floor and as the staff complement is small, there is a high possibility that no one would hear it. There is no planned training for all staff in the management of medical gases, or how to respond in the event of a liquid nitrogen burn or a low oxygen alarm in the building. Emergency services have not been informed that the centre is a healthcare facility with medical gases and liquid nitrogen on site. SLC T17 and T20.	occur prior to commencing licensed activity. The wall-to-floor seals should be reviewed and confirmation provided to the centre's inspector when this has been resolved. The PR should review the centre's processes regarding alerting staff and patients in the centre, as well as emergency services, to an emergency, with particular attention to the issues highlighted in this report. A report of actions taken should be submitted to the centre's inspector before licensed treatment commences. The PR should ensure that appropriate staff have had training in management of medical gases including liquid nitrogen, and all staff have had training in responding to medical gas or liquid nitrogen emergencies. Confirmation of this should be submitted to the centre's inspector before licensed treatment commences. A tabled update will be provided to ELP.	assessment will be provided to the inspector by the 10th January 2020. Safety signage regarding medical gases and liquid nitrogen storage were ordered and will be in place by the 6th January 2020. Photographic evidence will be sent to the inspector. The microbiological and air quality testing is scheduled for the 3rd January 2020 and therefore we should receive the results by the 10th January 2020. We will forward the results from this testing to the inspector once they are received. Contractors have been on site on the 19-20th December and now all areas wall-to floor have been resealed. M&E engineers are reviewing the nurse call system and will add a distinct signal to alert the staff for any emergency, including the men's production room. Confirmation will be sent to	

DH Health Building Note 00-10; 'Flooring' 2013.		the inspector once this is completed. All staff as part of their induction will complete an online course (organised by BOC) for the safe use, storage and handling of medical gases and cryogenics. Appointments to inform the Emergency services that the premises are a healthcare facility with medical gases and liquid nitrogen on site are orgnised for the w/c 06/01.	
2. QMS The PR and the clinic/quality manager have not worked under UK regulation or guidelines since 2013 and have not signed up to receive Clinic Focus emails. The inspection team is not satisfied that a system is in place to ensure that the centre's processes are up-to-date with regulatory guidance issued in Clinic Focus articles and recent updates to the Code of Practice, in particular guidance related to consent to legal parenthood, and screening guidelines for	The PR should ensure that all staff working in the centre are up to date with current legislation and regulatory guidance. The PR should develop a plan to address how he will ensure that changes to HFEA regulations and CoP guidance are considered and, where necessary, embedded in the centre's practices. This plan should include a review of past Clinic Focus articles, include a timeline for implementation, and should be submitted to the centre's inspector before licensed treatment	All staff working at In-OVO Fertility Clinic will be asked to read and familiarise themselves with the current HFEA CoP as part of their induction. The Clinic/Quality Manager will take the PREP test by the 10th January 2020 and the result will be forwraded to the inspector. The centre has now subscribed to the Clinic Focus newsletter. The PR will read the Clinic Focus newsletter of the past four months and will	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR should ensure that he has reviewed all relevant information, particularly related to the areas mentioned in this report. This will involve reviewing Clinic Focus articles, and also Chair's Letters and Chief Executive Letters, for a significant period of time,

donor. The centre has not established safeguarding processes and the identified lead has not had training at the appropriate level. SLC T12, CoP 25.33, 25.35 and 25.36. The centre does not have a documented procedure to follow in the event of clinical and non clinical emergencies, including staff availability and does not have a business continuity agreement with another licenced centre, in the event that they cannot provide licensed treatment, including storage.	commences. Th PR should complete the new HFEA PREP test, planned for release in early 2020 and the PR should also consider signing up for the PR 'buddy' system. It is acknowledged that both of these programs will not be available until early 2020, and the PR should liaise with the centre's inspector about gaining access to them. The PR should ensure that safeguarding processes are in place to protect patients and staff from harm where possible. The PR should ensure compliance with this requirement prior to the commencement of licenced activity. The PR should ensure that there are suitable arrangements in place to provide licensed treatment in the event of clinical and non-clinical emergencies, including staff availability. These should include processes for managing a clinical emergency, provision for the transfer of a patient and movement of storage vessels. The PR should ensure that there are	alert the appropriate staff in updating any relevant SOPs. All staff will receive an email notification for any amended SOP and will be requested to maintain their required level of competency. The PR will complete the new HFEA PREP test when this becomes available in 2020 and will update the inspector. The PR will contact w/c 06/01 two of different clinics that they are more experienced and seek for one of them to be assigned as his PR "buddy". A Business continuity plan is drafted and a copy will be available to the inspector by the 10th January 2020. The PR will contact a licenced centre and will arrange an SLA for the transfer of a patient and movement of storage vessels in case of clinical and non-clinical emergencies. Copies of the required SOPs will be forwarded to	longer than the past four months. The PR should confirm with the centre's inspector when this has been done. A release date for the new HFEA PREP test has not been confirmed. The centre's inspector will liaise with the PR when this happens. The PR buddy system is being developed along with the new test, and the PR can choose to take part in that program, or can contact other clinics directly. The executive will ensure that an ELP update is tabled if the centre's inspector is provided with a copy of the business continuity plan by 10 January. The PR has verbally informed the centre's inspector that he and the clinic manager have booked attendance at a safeguarding training event, and will provide

SLC 10. The centre does not have documented processes to cover; • management of storage of gametes and embryos, • patient support, • updated guidelines related to donor screening, • consideration of patient and donor travel history. SLC T33, T53.	documented processes for all activities authorised by this licence and other activities carried out in the course of providing treatment services, that do not require a licence. The PR should provide the centre's inspector with a copy of processes which address the areas identified in this report before licensed treatment commences.	the inspector prior to any licensed treatment commences.	confirmation once this is completed. The PR has also verbally confirmed that the required SOPs have been completed and will be provided to the centre's inspector by 10 January 2020. Further action required.
3. Equipment and materials Equipment is in the process of being installed and commissioned. Some validation documentation has been supplied to the centre's inspector but there are still some items outstanding, including the equipment monitoring system, and cryostore alarms and monitoring. SLC T24.	The PR should ensure that a complete set of critical equipment is validated. The PR should provide the centre's inspector with confirmation of the validation of all equipment. This must occur prior to commencing licensed activity. A tabled update on progress will be provided to ELP.	A copy of the validation of the Micromanipulator Rig, the Hot block and the Lab Refrigerator are attached. The remaining validation protocol for the Laminar Flow hoods will be forwarded to the inspector on the 13th January, when the Air Quality results are available following the test.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required, other than confirmation of validation of the flow hoods.
4. Counselling The documented processes for implications counselling, for all forms of third party family	The PR should ensure that counselling provision is compliant with statutory requirements and regulatory guidance.	A revised SOP detailing the processes for implications counselling for all forms of third party	The executive acknowledges the PR's response and commitment to implementing this

creation / donation, are not sufficiently detailed. Further evidence of the centre's processes regarding counselling have been requested but not yet provided. SLC T59, T60 and T61.	The PR should provide revised information detailing the processes for implications counselling provision to the centre's inspector on return of this report. The PR should ensure that activities where there is a statutory requirement to offer counselling are not undertaken until the counselling service has been deemed suitable by the executive.	family creation/donation is currently drafted and will be forwarded to the inspector by the 30th January 2020.	recommendation. Further action required.

‘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
None			

Further response from the Person Responsible to this inspection report
We have to thank the inspection team for their support and feedback and we look forward to work with them in the future in a constructive manner for the benefit of our patients.