Human Fertilisation and Embryology Authority

Minutes of the Licence Committee

Meeting held at Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
12 March 2015

Minutes – item 1

Centre 0341 (The Fertility & Gynaecology Academy) – application for initial treatment (including embryo testing) and storage licence

Members of the Committee:	Andy Greenfield (Chair, lay) Lee Rayfield (Deputy Chair, lay) Kate Brian (lay) Debbie Barber (professional)
Legal Adviser:	Philip Grey – Mills and Reeve
Members of the Executive:	Sam Hartley – Head of Governance and Licensing Trent Fisher – Secretary

Declarations of interest: members of the committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the committee:

- inspection report with PR response
- application form
- suite of additional information from the PR in response to the report
- CV of proposed PR
- CV of proposed LH

The committee also had before it:

- HFEA protocol for the conduct of Licence Committee meetings and hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted

- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA directions 0000 – 0012
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers.

Discussion

1. The committee noted that an application was received by the HFEA from The Fertility & Gynaecology Academy for an initial treatment (including embryo testing) and storage licence.

2. The committee noted that The Fertility & Gynaecology Academy is located at:

   57A Wimpole Street
   London
   W1G 8YP

3. The committee noted that at the time of inspection, the inspectorate reported a number of areas of non-compliance that required improvement including three critical, five major and three others.

4. The committee noted that the critical areas of non-compliance related to the suitability of the facility, practices and staffing.

5. The committee noted that the PR provided a detailed response to the investigation report and a significant number of documents. However, the inspectorate had had insufficient time prior to the Licence Committee meeting to review the responses and consider the documents submitted in support; to reconsider the application; and to arrange a further on-site inspection. Given the significance of the areas of non-compliance identified at the time of the initial inspection, and the date on which the applicant's responses had been received, the Committee considered that it was reasonable that the Executive had not yet been able to reassess the application.

6. The committee noted the inspectorate's recommendation that the committee decision on whether to grant the licence be adjourned until all the evidence had been adequately assessed and issues arising dealt with satisfactorily.

Decision

7. The committee agreed to adjourn its decision until the inspectorate has been able to reassess the centre's application. The committee urged the centre to work with the inspectorate on the timely and prompt provision of any further information.

8. The committee also noted that the application could be considered by the Executive Licencing Panel once all evidence is provided. However, the committee also reminded the inspectorate that, if concerns still exist, the application should be returned to the Licence Committee for consideration.

Signed: Date: 25 March 2015

Andy Greenfield (Chair)

Inspection 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 Licence Committee (LC) 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: 19 January 2015
Purpose of inspection: Issue of a licence to carry out Treatment (including embryo testing) and Storage.

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, Gill Walsh, Karen Conyers and Sheila Pike

Date of Licence Committee: 12 March 2015

Centre name	The Fertility & Gynaecology Academy
Centre number	0341
Centre address	57A Wimpole Street London W1G 8YP
Proposed Person Responsible	Dr Amin Gorgy
Proposed Licence Holder	Dr Adel Eskander

Brief description of the centre:

The Fertility & Gynaecology Academy is a private clinic in London. The proposed Person Responsible (PR) has applied for a Treatment (including embryo testing) and Storage licence. The centre proposes providing a full range of fertility services.

The clinic currently operates as a satellite of Boston Place (centre 0327).

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	450
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination (IUI)	50

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	✓

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);
- 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 inspection team has not been provided with sufficient information or assurance to conclude that:

- **the PR will discharge his duty under section 17 of the HF&E Act 1990 (as amended);**
- **the premises are suitable;**
- **the proposed practices are suitable.**

The LC is asked to note that at the time of the inspection, there were a number of areas of practice that required improvement including three critical, five major and three 'other' areas of non-compliance as follows:

Critical areas of non compliance:

- **The PR must ensure that suitable practices are used in the course of activities to be authorised by this licence and in other activities to be carried out in the course of providing treatment services that do not require a licence.**
- **The PR must ensure that licensed activities will be carried out in suitable facilities.**
- **The PR must ensure that personnel are available in sufficient number and are qualified and competent for the tasks that they will perform.**

Major areas of non compliance:

- The PR should ensure that prior to giving consent, gamete providers are provided with all necessary information.
- The PR should ensure the air quality in the processing areas is assessed and meets the requirements of Standard Licence Condition (SLC) T20.
- The PR should ensure that third party agreements (TPAs) with all third parties who will provide goods or services that influence the quality and safety of gametes and embryos are established.
- The PR should ensure that all critical equipment is validated.
- The PR should ensure that the use of a specific technique for selecting sperm for ICSI (PICSI) is validated.

'Other' areas that requires improvement:

- The PR should review the maximum level of activity for which the centre has been designed.
- The PR should ensure that quality indicators (QIs) include thresholds under which corrective action would be taken.
- The PR should ensure that, where possible, CE marked medical devices are used.

Detailed guidance was provided to the centre to assist them in addressing these non-compliances in the form of a table entitled 'areas of practice requiring action', which is included with these papers, along with the PR's response.

Recommendation to the Licence Committee

The centre has three critical and six major areas of concern. On the basis of the information provided to date in support of this application, the on-site inspection of the premises to be licensed and interviews conducted on the day of inspection with staff available at the centre, the inspection team considers that there is insufficient information available to be able to recommend that a Treatment (including embryo testing) and Storage licence is granted.

The inspection team has reached this conclusion as a result of the following:

- suitability of premises and facilities: due to the nature and extent of the building work on-going it was not possible to determine that the premises will be suitable;
- the centre's practices: a full suite of patient information and SOPs was submitted to the HFEA prior to inspection for assessment and feedback was provided on required improvements prior to the inspection. However, the centre's inspector was not informed that these documents remained under review and are not the final versions. A number of the documents submitted were unclear or inconsistent. When concerns were raised with the centre pre inspection about particular document content, SOPs were quickly revised and resubmitted. However, the inspection team is concerned that this somewhat open ended and iterative process indicates a lack of sufficient knowledge of requirements and/or experience of the provision of fertility treatment;
- the centre's staffing: there is not sufficient evidence to form an opinion on the suitability of the proposed staffing at the centre.

The inspection team directs the LC to Section 16(4) of the HF&E Act 1990 (as amended) which states that where the LC is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require him to provide.

On 19 February, the PR provided a detailed response to this report and submitted a significant number of documents to provide evidence of progress that has been made. These are included with the papers. The Executive recognises the amount of work that has been undertaken since the inspection. However, there is insufficient time to enable the Executive to review and evaluate these submissions, reconsider the centre's application, arrange and conduct a further on-site inspection and write a further report in time for this LC meeting which the centre has requested considers its application.

The inspection team recommends that the LC adjourns its decision until the Executive can reassess the centre's application.

At its meeting in January 2015, the Authority agreed to delegate consideration of initial treatment and storage licences to the Executive Licensing Panel (ELP), effective from 1 April 2015. The LC is asked to consider whether, in the event of adjournment, the application can be considered by an ELP in the future.

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 broadly compliant with HFEA requirements. This will ensure that patients receive treatment using the correct gametes or embryos.

What the centre can do better

The centre does not have a template witnessing sheet that demonstrates that all required witness steps will be recorded at the time the relevant procedure takes place, although all required steps are documented in its witnessing SOP (SLC T71; SLC T33b).

Donor selection criteria and laboratory tests

Screening of donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's proposed procedures for screening donors are partially 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/or embryos.

Payments for donors (Guidance note 13; Directions 0001)
The centre's proposed procedures are broadly 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's patient information and the SOPs submitted to the HFEA contain inconsistent and, in some cases, inaccurate information. For example:

- the centre's 'egg sharing programme information' states that the centre has 'the largest egg donation programme in the UK'. This is not correct and may be misleading to patients.
- the centre's 'egg donation recipient information' lists the tests that the *recipient* will be screened for prior to treatment. These include all tests usually only relevant to gamete donors and this information is inconsistent with that documented in the centre's SOP for patient screening.
- the centre's surrogacy patient information implies that the intended mother will be screened as an egg donor, even when she is not donating eggs. The information does not describe why the centre considers this necessary.
- the centre's 'screening of known sperm donors' SOP and sperm donation information do not reference the requirement to screen for chlamydia or, as recommended in professional body guidance, to screen for Gonorrhoea (SLC T52e and Guidance 11.22).
- the centre's SOPs directing activities prior to accepting sperm and egg donors state contraindications for donation in cases where the donor is not known to the recipient. However, it goes on to state that if the donor is known to the recipient, and at the recipient's discretion, these factors may not prevent known donation. The inspection team was concerned that these factors included known inherited conditions and current substance abuse.

During discussions with the inspection team on inspection, the PR demonstrated a satisfactory knowledge of donor screening requirements and explained that the SOPs and patient information submitted to the HFEA were still under review. However, the discrepancies observed and noted above led the inspection team to have significant concern about the centre's preparedness for both selection of donors and provision of treatment with donor gametes.

Payments for donors (Guidance note 13; Directions 0001)
The centre's 'egg donation donor' patient information states that donors can be compensated £750 per cycle, but that if overnight accommodation after egg collection is necessary, this will be arranged and paid for by the centre. The PR confirmed that this would be in addition to the £750 payment. The inspection team considered that this was non-compliant with General Direction 0001.

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)
On the day of inspection, extensive building work was ongoing at the centre. However some areas, including the laboratory suite, have been completed and were considered suitable. Suitable premises are important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The premises of the laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

Laboratory accreditation (Guidance note 25)
The 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
The centre's proposed systems to manage and monitor the prevention and control of infection are partially compliant with guidance.

Medicines management
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are partially compliant with guidance. The centre has provision in place for the management of controlled drugs and has been assessed by the Home Office for a licence to keep, prescribe and administer control drugs in the course of treatment at the centre.

Pre-operative assessment and the surgical pathway
The centre's proposed policies and procedures are partially 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; Directions 0003)
The centre's proposed procedures are broadly compliant with HFEA multiple births minimisation strategy requirements. The single biggest risk of fertility treatment is a multiple pregnancy and implementation of a suitable strategy is expected to minimise the incidence of multiple births.

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, to keep a record of this in the gamete provider's records.

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

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

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 the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's proposed procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;

- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly 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 TPAs are partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
This section is not applicable as the centre is not intending to undertake any satellite or transport arrangements if they are licensed.

Equipment and materials (Guidance note 26)
The centre will use equipment and materials that are compliant with HFEA requirements. Most 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 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 partially 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 all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to investigate all adverse incidents that may 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)
On the day of inspection, building work was ongoing including in the following areas: staff room, staff offices/counselling room and the basement corridor. The intended recovery area had not been refurbished or equipped. The 'scrub up' sink for the theatre had not been installed. Suitability of premises could therefore not be assessed fully and a further on-site inspection and assessment is required (SLC T17).

The air quality in areas where the processing of gametes and embryos exposes them to the environment has not yet been assessed (SLC T20).

The centre's licence application states that the maximum level of activity for which the centre has been designed is 450 cycles of IVF/ICSI/FET and 50 cycles of IUI/DI per year. The inspection team has concerns given the size and layout of the centre's premises and facilities that this may not be a safe maximum activity projection.

Infection control
Due to the extent of ongoing structural work and work still to be completed, the overall integrity of the clinical areas could not be assessed for suitable measures for effective infection prevention and control. The laboratory and procedure room were largely complete but still required the installation of key facilities such as a sink and taps. The area designated as a recovery room had not been refurbished and could therefore not be assessed.

The theatre's air quality has not yet been assessed via microbial monitoring.

The centre does not have protocols in place to perform pre employment occupational health screening. The centre's SOP for management of needle stick injury does not describe the local protocol to be followed in sufficient detail to provide assurance that in the event of a needle stick injury staff would have clear direction as to the actions to be taken.

The centre does not have an infection control lead in place.

Medicines management
The centre's medicine management SOP states that when a patient is not in a position to consent to the administration of medicines, medicines may be administered covertly if it is decided that it is in the patient's best interest. The inspection team does not consider that there would be any circumstance where providing medication covertly for IVF treatment would be acceptable (SLC T2).

The proposed PR stated on inspection that the centre would be prescribing and dispensing routine patient drugs from the centre. No evidence was available to demonstrate management of these activities including; SOPs, prescription proformas, evidence of oversight from a registered pharmacist or authorisation to dispense, control stock or how competence in the management of medicines and dispensing is to be assessed (SLC T2 and T12).

The cupboard in which the proposed PR stated he intended to store routine drugs for dispensing was a large two door filing cabinet which is currently in what is to be the recovery area. The final location of the medicines store could not be assessed for security. The inspection team does not consider the proposed storage cabinet to be secure or fit for purpose.

The concerns documented above led the inspection team to have significant concerns about intended practice at this centre and suggests a lack of insight into the requirements for appropriate medicine management.

Pre-operative assessment and the surgical pathway
The assessment of the suitability of the pre, peri and post operative surgical pathway could not be performed on inspection as the theatre and recovery areas were not fully equipped. Documentation to support the process for assessing and monitoring patients during the pre, peri and post operative pathway and how these activities are to be

recorded was not available so could not be assessed for suitability.

The centre's approved and submitted 'operating room nurse protocol' details the requirement for a number of surgical instruments to be available which would not normally be associated with egg collections, or for surgical sperm retrieval procedures. The list includes scalpels, artery forceps and scissors described as being 'for vaginal surgery' and a set of cervical dilators the size and range of which appear more suitable for gynaecological procedures other than those associated with IVF. The inspection team is concerned that the document provide to the HFEA for consideration is somewhat generic in nature and does not reflect the intended practice at this centre or surgical procedures to be conducted under the level of sedation and analgesia suitable for a remote site and suggests a lack of insight into the requirements for safe surgical practice.

Multiple births (Guidance note 7; Directions 0003)
The centre's patient information and SOPs submitted are inconsistent with respect to the centre's elective single embryo transfer criteria.

Traceability (Guidance note 19)
The centre's traceability SOP does not include the requirement to record the equipment used in processing gametes and embryos (SLC T99).

Quality management system (QMS) (Guidance note 23)
QIs have been established for all licensed activities but thresholds, under which corrective action would be taken, have not been established in all cases. This is important to ensure that centre staff have a clear understanding of the expected quality they should expect to achieve and that should outcomes fall below the accepted threshold this is identified in the course of routine audits (SLC T35 and T36).

Third party agreements (Guidance note 24)
TPAs have not been established with all third parties that will provide goods or services that influence the quality and safety of gametes and embryos, including the courier to be used to transport gametes/embryos (SLC T111).

Equipment and materials (Guidance note 26)
The centre has purchased and installed all laboratory equipment required with the exception of the microscope required for semen analysis.

Sperm will be prepared in a Class I hood. The inspection team was concerned that a Class I hood would not offer the protection to the operator necessary when processing semen samples. The PR explained that he had conducted a risk assessment demonstrating the suitability of this hood for its intended purpose prior to installation (SLC T23).

The centre has not yet validated its critical equipment (SLC T24).

The centre submitted a list of consumables and reagents to be used in the laboratory. A brief review of the list demonstrated that one of the test-tubes intended for use is not CE marked (SLC T30).

Process validation (Guidance note 15)
A specific technique for selecting sperm for ICSI (PICSI) intended to be used at the centre has not been validated (SLC T72).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

What the centre could do better

Person Responsible (Guidance note 1)
The initial HFEA PR Entry Programme submitted on behalf of the PR bore significant similarities to another PREP submitted by another person in 2014. It was explained that although the PR had answered the PREP questions, a consultant company had written the answers and submitted the PREP. This company was also involved in the submission of the similar PREP earlier in 2014. The PREP is an important method by which the suitability of the PR can be assessed and the Executive did not consider this to be a suitable practice. The PR was asked to complete a second PREP and the answers were discussed in detail on inspection. The PR has now successfully completed a second HFEA PREP (PREP number T/1267/82).

Staff (Guidance note 2)
The centre is not compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

The proposed PR explained that he is not planning to recruit the necessary staff until the HFEA licence application process has progressed.

The centre currently employs one embryologist on a locum basis. The proposed PR is planning to recruit one more embryologist, but may use locums in the interim should a licence be granted (SLC T12).

On the day of inspection, an experienced fertility nurse was present, this was her first visit to the centre and she is currently employed elsewhere. The registered nurse listed on the centre's application has no experience of HFEA licensed activity and is currently on maternity leave until the autumn of 2015. The centre currently employs one other registered nurse who has been in post for approximately four months and has no relevant fertility nursing experience. The proposed PR stated that the plan was to recruit a senior nurse manager and a health care assistant (SLC T12).

The application form lists the proposed LH, Mr Eskander, as the accredited consultant. Mr Eskander is on the Obstetrics and Gynaecology specialist register but explained on inspection that he has no specialist knowledge in IVF treatment and that his role would be managerial not clinical. The PR is the only doctor at the centre with IVF experience but as he is not on the GMC specialist register, the centre will not have access to a registered medical practitioner to advise on and oversee medical activities as recommended in HFEA Guidance at section 2.8 of the Code of Practice.

The PR has not yet identified the level of anaesthetic service that will be required for performing surgical procedures (SLC T12).

Job descriptions for the proposed senior nurse, registered nurse and health care assistant have not been developed (SLC T13).

An induction SOP and competence framework is in place but has not been completed by any of the centre staff currently employed. Staff folders were reviewed for two members of staff: one nurse and the medical secretary. No evidence of mandatory training or competence assessment was seen. There was no evidence of staff currently in post having been trained in basic life support, surgical procedures or post operative recovery or how, prospectively, staff conducting procedures under conscious sedation will be trained or their competence assessed (SLC T15).

The locum laboratory manager is HCPC registered, but does not have a permanent contract with the centre. It is not clear therefore if the centre will have access to a nominated registered scientist to advise on and oversee scientific activities (SLC T14 and Guidance 2.14).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's proposed procedures for taking into account the welfare of the child are broadly compliant with HFEA requirements. This is important to ensure that the centre takes into account 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 before treatment is provided.

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

What the centre could do better

Welfare of the child (Guidance note 8)
The centre has submitted a policy and a SOP for conducting welfare of the child (WoC) assessments. These are very similar and it is not clear why both are necessary. The SOP describes in detail the implications of using donor sperm and the importance of implications counselling: it is not clear how this links to WoC assessment.

There is an inconsistency between the patient information and the WoC SOP. Information for patients states that if there are facts the patient does not wish their partner or family doctor to know, they can write in confidence to their clinician at the centre and that the disclosed information will be kept confidential, as required by law. However, the SOP states that this confidence may be broken in certain circumstances. This is not made clear in the patient information.

The WoC SOP states that 'if a patient's demographics are outside of the clinic's limits their case is discussed by the team'. The inspection team asked the PR what this statement meant on the day of inspection but the PR was not able to provide a clear response. It is acknowledged that age is a common demographic and that it may be appropriate to consider whether treatment should be offered to some patients on the basis of their age and that this may be relevant to WoC however, the wider implications of considering the impact of other common demographics (gender, ethnicity for example) raised concerns in terms of ensuring that patients are treated fairly and in a non-discriminatory way.

Safeguarding
The PR is currently the safeguarding lead at the centre, but has not received any safeguarding training. No evidence of training was available in files of existing staff reviewed on inspection. However, the inspection team was informed that the proposed counsellor is a safeguarding trainer.

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 will be compliant with HFEA requirements. 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 is 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 serious genetic condition.

The centre will ensure that people seeking embryo testing are given suitable information, and have access to advice from a clinical geneticist and a counsellor.

What the centre could do better

No evidence has been provided that there will be suitably trained and experienced staff to perform embryo biopsy (refer to 'staffing' section of this report).

2. The experience of patients

Treating patients fairly
Counselling
Egg sharing arrangements (Guidance note 12; Direction 0001)
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 appeared broadly 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 (see WoC comments above).

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 and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's proposed procedures for egg sharing arrangements are broadly 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).

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

Complaints (Guidance note 28)
The centre's proposed procedures are broadly 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 partially 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

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's patient information for those considering egg sharing states that if less than 10 follicles develop, the egg sharer has the option to donate all of her eggs to the recipient and then return for a free cycle of treatment. General Direction 0001 states that egg donors who receive a benefit should be provided with that benefit in the course of the donation cycle unless there is a medical reason why they cannot be.

The inspection team did not consider that information to egg sharer's made it sufficiently clear that the patient could withdraw consent at any time up until the point the embryos were transferred to the recipient, without financial penalty.

Surrogacy (Guidance note 14)
The inspection team did not consider that the centre's surrogacy patient information was sufficiently clear or detailed to provide adequate information to patients, including options in relation to legal parenthood. The leaflet also states that in host surrogacy the commissioning couple "literally rent the womb of the surrogate host". The inspection team considers this phrase to be unacceptable because it is illegal to pay a surrogate in the UK, although reasonable expenses can be reimbursed. The PR agreed and explained that the leaflet was still under review.

The centre does not have a SOP to direct surrogacy treatment and the inspection team was not assured that centre staff were fully aware of the complex requirements and implications, for example around legal parenthood, that are involved in surrogacy treatment.

Complaints (Guidance note 28)
There is inconsistency between the centre's patient information, a patient notice in the waiting room and the centre's complaints policy in terms of the timeframe for complaint responses. Also, the patient information leaflet states that responses will be provided within 40 working days. The proposed PR is encouraged to consider if this timeframe demonstrates adequate responsiveness to patient complaints.

Confidentiality and privacy (Guidance note 30)
The centre's quality manual states that IT security protocols are in place to ensure confidentiality of electronically stored sensitive data such as patient records. The centre is also planning to communicate with patients via e-mail. However, the quality manager confirmed that no IT security protocols are yet in place (SLC T44).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed procedures for providing information to patients are partially compliant with HFEA requirements. This is important to ensure that the centre will give 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

The centre provided a suite of patient information leaflets prior to inspection. The

inspection team conducted a full audit and noted several issues and concerns, as documented elsewhere in this report and also including:

- the IUI patient information sheet lists the risk of OHSS and multiple pregnancies as a disadvantage of IUI compared to IVF;
- the general patient information leaflet lists the fertility treatments that will be available at the centre and includes intra-cytoplasmic morphologically selected sperm injection (IMSI) and timelapse microscopy using an Embryoscope. The centre does not have the necessary laboratory equipment to offer these services.

On inspection, the proposed PR explained that these leaflets are not the final versions and that patient information is still under review.

The centre currently operates as a satellite of Boston Place. Prior to this, the centre had a satellite arrangement with City Fertility (centre 0324) which terminated in November 2014.

The centre's website was reviewed prior to inspection. Information included details of the satellite arrangement with City Fertility but the presentation of success rates was not considered to be compliant with the guidance of the HFEA Chair's letter (CH(11)02). For example, the website does not provide raw numbers, it only provides success rates as percentages. This is particularly important where only small numbers of cycles are provided. For example it quotes a success rate of 100% for DI treatment in under 35 year olds. It also does not provide details of what the '100% success rate' relates to (e.g. clinical pregnancy rate or live birth rate, per cycle started or insemination or the year). This raises concerns that the presentation of success rates on the website could be misleading to patients.

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 broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

What the centre could do better

Consent (Guidance note 5)
The centre's 'local policy on consent' states that if a patient has given valid verbal consent but is physically unable to sign the form, this will not prevent treatment being given. It does not detail that in these cases, another person must sign on their behalf, provided that the person giving consent is present and the signature is witnessed and attested to by at least one other person.

It also states that if a patient lacks permanent mental capacity, treatment may still be given if it is in their best interests. It is not clear in what circumstances this may occur for the patients and donors being treated under the proposed licence.

In general, the centre's SOPs are not sufficiently detailed to adequately direct the process

of giving patients an opportunity to give fully informed and effective consent, but the PR explained that SOPs are still under review.

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 will have respect for the special status of the embryo when conducting licensed activities.

- licensed activities will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be 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 will only be 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's proposed procedures for using embryos for training staff are partially 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 **Use of embryos for training staff (Guidance note 22)** The centre's training SOP is very generic; it states what must be done but not details of how this will be managed in practice.

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.

Reponses from the Person Responsible to this inspection report

The FGA team is surprised at the negative tone of the inspection report and that the HFEA Inspection Team has not given us any scope to provide evidence to demonstrate to the Authority that we have worked hard to resolve the matters raised at inspection. It is disappointing that the HFEA Inspection Team does not consider that they have time to review progress made before the March Licence Committee.

We are also disappointed that the report from the inspection has been provided to us three weeks after the date of inspection allowing us 8 working days to respond.

It is our view that historical matters that have been resolved to the satisfaction of the HFEA Inspection Team remain unnecessarily detailed within the report under the heading "what the centre could do better" and yet there are no action points for the Centre - refer to first bullet point under Screening of donors on page 7 & the paragraph under Person Responsible on page 13. We consider that these resolved matters should not be detailed in the report as they are no longer points for action.

After discussion with the FGA team, we would like to request that egg sharing is removed from this application. This treatment will be applied for at a later date once processes are fully developed, reviewed by the HFEA Inspection Team and embedded.

There are several factual inaccuracies within the report which we would like to bring to the attention of the HFEA Inspection Team and the Licence Committee:

Page 7 – Screening of donors:
First bullet point – we acknowledged that this was an error at a meeting with the HFEA Executive on 21 November 2014; the patient information sheet was revised and approved on 24 November 2015. This error no longer remains and therefore we did not expect this resolved matter to be in the report under the heading "what the centre could do better".

Page 7 – Payments for donors:
We anticipated that arranging and paying for accommodation for egg donors following egg collection would be a rare occurrence. The intention was to cover the cost of the hotel directly and not reimburse the donor, however being guided by the HFEA Inspection Team at the inspection we already agreed on the day and have removed this from the patient information sheet.

Page 10 and page 11– Safety and suitability of premises and facilities & Infection control first paragraph: The scrub sink for theatre had been installed long before the day of inspection – it is housed within the Theatre itself. An additional sink upon entry to the

procedural suite had not been installed by the time of inspection; however the critical scrub sink was in place at the time of inspection.

Page 11 – Infection control third paragraph: Page 5 of the Centre's Standard Precautions for Infection Control SOP (NURSOP08) describes the local policy for management of a needle stick injury. We felt that this adequately reflected local policy however the SOP has been further revised by the newly appointed Senior Nurse Manager. The recovery room is not and will not be refurbished.

Page 11 - Occupational Health fifth paragraph: FGA has established a TPA with Occupational Health Services at 1 Harley St. We have pre-occupational health questionnaire from Peninsula; the company that takes care of our employment matters and health and safety.

Page 11 – Medicines Management:
Third paragraph – The cupboard used to store routine drugs is not a filing cabinet – it is a locked cupboard. However, the Centre will outsource the majority of fertility medication to a home-delivery pharmacy company. A small stock of emergency medication will be stored in a locked cupboard within a locked room in the basemen with other supplies.

Page 11 – last paragraph; the theatre and recovery were not fully equipped:
The theatre is fully equipped including operating table, anaesthetic machine, monitor including carbon dioxide, suction machine, resuscitation trolley, defibrillator, injection pump, egg collection aspiration machine and ultrasound machine.

As explained during the inspection we plan to do one egg collection a day initially using the operating/recovery trolley that was located in the procedure room on the day of inspection. One smooth running is confirmed we will buy another one. We have two recovery bays. Each bay will host a recovery trolley and two chairs. The chairs and the table were arranged in the recovery room on the day of inspection for the comfort of the inspection team. On the day of inspection the recovery monitor was already in the recovery room. In addition the recovery room has a small cupboard a desk and a computer.

Page 13 – Person Responsible:
The PR has successfully completed an HFEA PREP to the satisfaction of the HFEA Inspection Team before the inspection. We do not understand why the first paragraph appears under the heading "what the centre could do better" as this matter was historical and is resolved to the satisfaction of the HFEA Inspection Team.

Page 13 – Staff

The centre has issued a contract of employment to the current Locum Embryologist to commence employment on 30 March as Laboratory Manager. The employment start date is specifically at the request of the Locum Embryologist.
The centre has employed the fertility nurse who was present on the day of inspection. That was not her first visit to the clinic. She was previously interviewed and a job offer was already being discussed. She has been appointed as Senior Nurse Manager and the HFEA Inspection Team has been informed.
Evidence to satisfy the competence of both the newly appointed Senior Nurse Manager and Laboratory Manager have been requested from previous employment (that of the Laboratory Manager is on file).
The Centre's other registered nurse has relevant fertility nursing experience after working for an IVF unit in Italy.
Dr Eskander, the proposed Licence Holder, is sufficiently experienced and qualified to be regarded as the Centre's Accredited Consultant. Dr Eskander is willing to confirm this with the HFEA Inspection Team as required. Please find vthe attached letter from Dr Eskander.

Additional responses and updates:

Page 3 and page 11 - centres anticipated activity levels. The initial licence application form asked us to "Please indicate the maximum level of activity (number of treatments) for which your new unit has been designed". However the inspection report details "Centre's anticipated activity levels". These are different questions. Our initial anticipated activity level is 150 cycles of IVF/ICSI/FET and up to 20 cycles of IUI.

Page 6 - Witnessing and assuring patient and donor identification: Relevant LABFORMS and NURSFORMS have been developed and approved to record witnessing steps as noted in the centre's post inspection action plan provided to the HFEA Inspection Team on 5 February 2015.

Page 7 – Screening of donors:
Second bullet point - the SOPs and patient information have been reviewed and revised to reflect consistency and screening required in accordance with HFEA and professional body guidance. These documents are available to the HFEA Inspection Team upon request.

Third bullet point – This patient information has been reviewed and revised in order to clarify that no screening tests are required for the intended mother (commissioning female) in the situation where she is not the provider of eggs. This document is available to the HFEA Inspection Team upon request.

Fourth bullet point – Both the patient information and SOP have been reviewed and revised by the FGA Team to include the requirement to screen for both Chlamydia and Gonorrhoea. Both are available to the HFEA Inspection Team upon request.

Page 11 – The Centre does have a local infection control lead in place. The HFEA Inspection Team is aware that the Senior Nurse Manager who was in attendance at the inspection is now employed by FGA and is the infection control lead as detailed in the centre's SOP.

Page 11 – Medicines Management:
First paragraph – the SOP has been reviewed and revised by the newly appointment Senior Nurse Manager and is available to the HFEA Inspection Team on request. The paragraph in question related to the possible need for emergency medication to be administered whilst the patient is under sedation. This however is covered by the pre-operative consent and therefore has been removed from the SOP.

Page 11 – Pre-operative assessment and the surgical pathway
Relevant NURSFORMS have been developed and approved to document pre-operative assessment and the surgical pathway as noted in the post inspection action plan provided to the HFEA Inspection Team on 5 February 2015.

Second paragraph: The set of surgical instruments in question are used in the rare occasions of uncontrolled vaginal bleeding or cervical stenosis. As these occasions are very rare, the instrument lists in the SOP have been revised. We are surprised that this is the only post inspection submission that was picked on. All other positive submissions as a result of the hard work of the FGA Team were completely ignored and not mentioned in the report. All surgical instruments are single-use, disposable and traceable items.

Page 12 - Multiple births: We disagree that the centre's patient information and SOPs are inconsistent. The patient information provided to potential patients at initial enquiry does not intentionally detail the specific eSET criteria. However, we have removed this specific patient information sheet as more detailed multiple births information is detailed within the IVF patient information.
Page 12 – Traceability: LABSOP18 has been revised and available to HFEA Inspection Team on request.
Page 12 – Quality management system: SOP revised and thresholds are detailed and available to HFEA Inspection Team on request.
Page 12 - Third party agreements: TPA with the selected courier is dually signed and in place.
Page 12 – Equipment and materials: As the HFEA Inspection Team is aware, the centre's critical equipment had been validated with the exception of air quality within the flow hoods. The aspiration pumps and tube warmers have been validated since the

inspection. Air quality testing and microbial testing has been carried out on 17 February and therefore the outstanding validations are now complete by and the reports available to the HFEA Inspection Team along with this response to the report.
With regards to CE marked consumables, all CE products have been sourced. The oocyte collection tubes (14ml) will be from Vitrolife and we will not use 5ml tubes until a CE marked version comes on the market.

Page 12 – Process Validation: The technique of PICSI has been validated - LABPVAL19 and LABSOP28 are available to the HFEA Inspection Team along with this response to the report.

Page 14 – Paragraph 2; Anaesthetic service:
We have a TPA with "Sedation Solutions" for our sedation services.

Page 14 – Paragraph 4; basic life support:
We usually arrange for a refreshing course every year. The last course was on 28 November 2013. As we were busy with the preparation for the HFEA inspection and the provider company was not flexible with the dates near Christmas and New Year the arrangement slipped through but the staff are booked for an all comprehensive mandatory training course.

Page 14 – Welfare of the child: As noted in the report, there is no need for both an SOP and a policy on Welfare of the Child and the centre has removed CLINSOP22 from the Quality Management System.
The patient information has been revised to clarify that information provided as part of welfare of child assessment may be discussed with the centre's team.
FGA's Welfare of the Child policy states "Those seeking treatment are entitled to a fair assessment. FGA will consider the wishes of all those involved, and the assessment must be done in a non-discriminatory way. In particular, patients should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age." The intention of including "if a patient's demographics are outside of the clinic's limits their case is discussed by the team" was to ensure that FGA does not discriminate on the basis of age alone. It is our view that this paragraph of the inspection report is not reflective of the centre's welfare of the child policy, is taken out of context and factually incorrect. However, as stated above, the SOP has now been removed from the centre's quality management system and therefore this is no longer an issue.

Page 15 – Safeguarding: The newly appointed Senior Nurse Manager is the local lead for safeguarding and has received safeguarding training within the NHS. The SOP has been updated. In addition, mandatory training including safeguarding has been arranged for all staff.

Page 15 – Embryo testing: The centre has issued a contract of employment to the current Locum Embryologist to commence employment on 30 March as Laboratory Manager. The employment start date is specifically at the request of the Locum Embryologist. She is suitably trained and experienced to perform embryo biopsy.

Page 17 – Egg sharing and surrogacy: Please see comment at the start of this response regarding our request to remove egg sharing from this application. The surrogacy patient information document has been revised and a surrogacy SOP has been written - both are available to the HFEA Inspection Team upon request. The prospective Person Responsible, Senior Nurse Manager, Lead Administrator and Quality Management Consultant attended the recent HFEA consent and multiple births workshops.

Page 17 – Complaints: There is no clear statutory requirement within the HFEA or CQC regulations. The only time-frame stipulated to responding to requests for information is detailed within the Data Protection Act at 40 days following a request. However, we have amended the patient information and SOPs to reflect that all formal complaints will be acknowledged within 48 working hours of receipt of the complaint. The patient should expect a reply within 20 working days unless the investigation is still ongoing when an interim report will be sent to the patient. The final report will be sent within 5 days of completing the investigation.

Page 17 – Confidentiality and Privacy:
Our IT supportive company, West One Technical has prepared our IT security protocols.

Page 18 – Information: The IUI patient information sheet has been reviewed and revised and is available to the HFEA upon request. The general patient information leaflet has been revised and is available to the HFEA Inspection Team upon request. However, we would like to note that whilst time-lapse microscopy will not be available at FGA immediately after licensing, FGA is currently a satellite centre of an HFEA licensed centre who provides this technology and therefore time-lapse is currently available to patients of FGA.

We apologise if the success rates displayed are not considered compliant with HFEA guidance. However this data was provided directly to FGA by the other HFEA-licensed centre under strict instructions to publish without alteration as guided by their HFEA inspectors during their last inspection.

Page 18 – Consent: The centre's GENSOP21 Local Policy on Consent has been removed from the Quality Management System. GENSOP52 has been reviewed and revised and is available to the HFEA Inspection Team upon request. The HFEA February Clinic Focus released subsequent to the inspection provides additional guidance and new forms to enable all clinics to demonstrate compliance with provision of information prior to obtaining fully informed consent indicating that other clinics might also benefit from

the guidance and new forms. The new forms will be incorporated into FGA's SOPs for providing information and taking consent. The prospective Person Responsible, Senior Nurse Manager, Lead Administrator and Quality Management Consultant attended the recent HFEA consent and multiple births workshops. Consent training and competency assessment is the responsibility of the Senior Nurse Manager.

Executive response

The Executive acknowledges the PR's response to this inspection report. The PR is reminded that this report represents analysis of information prior to and findings on the day of inspection.