New Premises Site Visit Report

Name of Applicant	Mr. Michael Ah-Moye
Name and Address of Proposed Premises	Herts and Essex Fertility Centre, Bishops College, Churchgate, Cheshunt, Hertfordshire, EN9 8XB Centre 0030
Has the applicant been licensed before	Yes
If yes: Centre Number and Address of previous premises	Essex Fertility Centre, Holly House, High Road, Buckhurst Hill, Essex 1G9 5HX Centre 30
Inspector(s)	Janet Kirkland (HFEA)
	Dr. Andrew Leonard (HFEA)
	Joint new premises inspection performed with Health Care Commission registration visit
Date of visit	Monday January 7th 2007
Date of any previous visits to these premises	23rd October 2007 23rd November 2007

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

Essex Fertility Centre has been licensed since 1992 and is a large sized clinic providing a variety of licensed treatments to self-funded and NHS patients.

The team at Essex Fertility Centre have moved to new custom built premises and are now known as "Hertfordshire and Essex Fertility Centre". The premises have been inspected by the HFEA and were issued with a licence to store gametes and embryos from 26th November 2007. This was agreed by Licence Committee on 29th October 2007.

Patients under the care of the fertility team have been informed of the relocation and have, where necessary consented to their stored gametes/embryos being transferred to the new premises. The transfer of gametes/embryos to the new premises was completed on 28th November 2007.

The refurbishment of the new premises is now almost complete and the Person Responsible requests that the current licence to store be varied to include treatment. The appropriate fee and application have been received.

The entire fertility team apart from one part time administrator relocated to the new premises on 1st December 2007. No treatment services other than storage of gametes/embryos have been performed since this date and the team have used this time to source and fit equipment in the centre, update procedures, protocols and patient information, perform audits and attend training events such as:

- Basic life support
- Customer care
- Fire
- Association of Clinical Embryologists winter conference

The premises were seen to be pleasant and well presented. Consideration had been taken for patient dignity and privacy.

Opening hours will be from 0900hrs - 1700hrs Monday to Friday and Saturday and Sunday as required.

The team expect to perform approximately 700 treatment cycles per year.

The PR has been in position since 1992 and is based at the centre full time. He has completed the Person Responsible assessment programme.

Summing up meeting notes

The assessor for the Health Care Commission discussed with the centre team actions required to be completed following the registration visit which took place on 7th January 2008. These included:

- CCTV Policy and procedure
- Completed risk assessments for all areas
- A copy of the Registered Managers job description
- Emergency out of hour's number to be included in telephone answering service.
- Audit schedule for 2008/2009
- Evidence of a medical records tracking system
- Key cupboard policy including signing in and out procedure to ensure an audit trail is maintained.
- Evidence of third party contracts when available
- Evidence of servicing of equipment in particular the anaesthetic machine prior to use.
- Policy and procedure for handling alert letters and medical device information including registration with MHRA to receive alert letters from Medicines Control Agency.
- Copies of conscious sedation protocols and drug regimens.
- Policy stating no research is carried out at the establishment and explaining the link with Guys and St Thomas's Hospital

In addition prior to variation of the licence the HFEA executive requested assurances from the Person Responsible on January 8th 2008 that the following issues have been addressed satisfactorily:

- Third party agreements to be completed

- Records control policy/procedure to be created regarding the movement of patient files after removal from the main filing system

- Security policy/procedure to be created regarding the use and response to the "Panic" button in the reception area

- Policies/procedures to be updated taking into account the new premises. Two in particular:

    1. The pathway for patient's semen samples from production to laboratory.
    2. Air Quality monitoring

- Control of Substances Hazardous to Health (COSHH)/Health and Safety notices to be displayed where required.

- Validation of equipment.

- A risk assessment of activity levels.

The Person Responsible responded via email on January 14th 2008 " We confirm that the issues raised in the report will be addressed in full before any treatment is undertaken in the clinic".

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence of:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Knowledge of the legal requirements and COP

Summary of Findings
The Person Responsible has been in position since 1992. An organisational chart was evidenced at the inspection. The Nominal Licensee is the Registered Manager for the Health Care Commission (HCC) and he, the Nurse Manager and the Person Responsible were present for the inspection. The entire fertility team apart from one part time administrator have relocated to the new premises and the Person Responsible is confident that the team are adequately resourced to provide the treatment services offered. The Nominal Licensee is the Quality Manager and the team are working towards an ISO9001 quality management system. Staff interviewed at previous inspections were aware of the incident reporting system. The Person Responsible has considered contingency measures in the event that the service is terminated unexpectedly and has established a specific relationship with Bourn Hall for such situations. This has been documented. A business plan is in place and the team expect to perform approximately 700 treatment cycles per year. The Person Responsible has completed the Person Responsible Entry Programme. The Nominal Licensee is an external scientific inspector for the HFEA.

Areas for improvement
A risk assessment to be performed regarding the number of treatment cycles which can be performed at the centre. Third party agreements to be completed. Completed risk assessments for all areas.
Points to consider/action for next inspection
Evidence of third party agreements. Evidence of risk assessments.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services

Summary of Findings
Patient's notes were seen to be filed in a lockable filing system within a room which is locked when not in use. The inspection team were informed that the reception area will be manned at all times. The reception area is alongside the waiting area and the team are aware that calls received at reception can be overheard in the waiting area. Patient calls of a confidential nature are transferred to an office behind the reception which is protected by a sound proof wall. The inspection team were informed that all members of staff sign a confidentiality agreement. A form was evidenced on inspection. Treatments to be offered include: • Full investigation of the causes of infertility • Intrauterine insemination • Ovulation induction and monitoring • In Vitro Fertilisation (IVF) • Cryopreservation of gametes and embryos • Frozen embryo replacement: (FER) • Male factor infertility: Intracytoplasmic sperm injection (ICSI) • Surgical sperm retrieval • Blastocyst Transfer Programme • Gamete and Embryo Donation, Egg Sharing, Sperm Sharing • Assisted hatching

- Surrogacy
- Counselling

Surgical treatments will be performed under conscious sedation.

Clinical procedures at Holly House Hospital were performed under general anaesthetic. The team must ensure that all patients, prior to embarking on treatment are aware that this form of anaesthesia cannot be performed in the new premises; procedures will be performed under conscious sedation. Patient information submitted for the inspection refers to "deep sedation". The Person Responsible must ensure that patients are aware and understand the terminology.

Should a patient emergency arise and a patient needs to be transferred for emergency treatment, arrangements are in place with Harlow.

The inspection team considered that patients privacy and dignity had been taken into account in the design of all patients areas.

A complaints notice was seen to be displayed in the waiting room.

Patient feedback is gathered by use of a questionnaire, a patient forum on the website and a comments box which was seen to be located in the waiting room. An audit of patient feedback was evidenced on inspection.

Counselling is offered to all patients and up to three sessions are offered free of charge. Counselling is mandatory for patients who are giving or receiving donated gametes. Patients can contact the counsellor through the centre or directly on a mobile number.

On average, patients receiving implications counselling attend for one session and for therapeutic counselling a maximum of three sessions.

Appointments with the counsellor will be at Holly House Hospital or at the counsellor's home.

Highlighted areas of firm compliance

Patients notes were seen to be filed in a lockable filing system within a room which is locked when not in use.

The inspection team considered that patients privacy and dignity had been taken into account in the design of all patients areas.

Patient feedback is gathered by use of a questionnaire, a patient forum on the website and a comments box which was seen to be located in the waiting room.

Areas for improvement
A policy/procedure to be put in place regarding patient file management when files have been removed from the main filing system. A policy/procedure to be put in place regarding the use and response to the “Panic” button situated at reception. The centre team to audit counselling update with regards to appointments not being available at the new premises.
Points to consider/action for next inspection
Review file management procedure/protocol Review panic button procedure/protocol Review patient feedback Review counselling uptake

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Summary of Findings
The premises are situated adjacent to council buildings in Cheshunt. They have been sensitively designed and renovated, to produce a pleasant environment which appears to be both practical and comfortable. Consideration has been taken of patient privacy and dignity. The centre has a designated car park with barrier controlled access. CCTV monitoring is in place. All external doors and windows are connected to a contact and vibration activated alarm system. The alarm system and CCTV are monitored by a contracted security company. The effectiveness of this system has been evidenced to the centre team as they were alerted by the security company to a window being broken. The entrance to the building has disabled access and is controlled by intercom. There are four consulting room and two treatment / scan rooms on the premises. The procedure room is next to the laboratory. The recovery area is situated opposite the procedure room and has four bays, each will have access to oxygen, suction and patient monitoring system. An emergency trolley is in place within the recovery area. The male production room had a patient alarm bell installed. The storage facilities were inspected previously by the HFEA and a storage licence was issued effective from 26th November 2007. The laboratory was seen to be well equipped. Installation, servicing and validation of all equipment is expected by the PR and his senior staff to be completed by 21st January 2008. The electronic 'IVF witnessing' system was seen to be installed on key pieces of equipment. This mode of witnessing will be risk assessed prior to use and the centre will start treatment services using manual witnessing, as it used in its old premises Dewar alarms were seen to be in place and connected to a dial up facility.

Low level oxygen alarms are in place and can be heard locally. These will, in the future be connected to the main alarm system.

A protocol/procedure for alarm response is in place.

Highlighted areas of firm compliance
The premises were considered to be fit for purpose. The design and furnishings were of a high standard and consideration had been taken for patient access, comfort, privacy and dignity. The laboratory was considered to have been designed and equipped to a high standard in accordance with the Code of Practice, 7th Edition.
Areas for improvement
Control of Substances Hazardous to Health (COSHH)/Health and Safety notices should be displayed where required. Emergency trolley to be fully stocked and equipped prior to treatments being performed at the centre. Installation, validation and servicing of equipment to be completed.
Points to consider/action for next inspection
Review maintenance and service contracts. Review protocols and procedures.
The standard of the premises and equipment
On completion of installation, validation and servicing of equipment the inspectorate considered that the premises and equipment would be fit for purpose.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and to the HFEA
Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

Summary of Findings
Patient information seen on previous inspection was considered to be of a good standard and appeared to be easy to understand. Documents, patient information and protocols observed by the inspectorate on previous inspection were seen to be version controlled. Information, protocols and procedures are currently under review and are being updated to take into account the relocation to new premises. Patients have been informed of the move to new premises.
Outcome of audit of records
An audit was not performed
Highlighted areas of firm compliance
Prior to the transfer of patient embryos and gametes the Person Responsible was in close contact with the HFEA and ensured that patients were well informed and consents were in place. A full audit of gametes and embryos in storage was performed.
Areas for improvement
The register department at the HFEA reported that there are issues with the completion of forms submitted to the HFEA. This appears to be due to the software being used by the centre. The Nominal Licensee is aware of the problems and a solution is currently being sought. He will keep the registry department informed of progress made. The telephone out of hours message to include a number for patients to call in the event of an emergency.
Points to consider/action for next inspection
Review patient information

Check with registry regarding the accuracy and submission of information from the centre.
The standard of information provided
Information submitted for the inspection was limited as it is currently being re-printed to take into account the new premises.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Laboratory processes and practice
- Clinical practice
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Summary of Findings
Three consultants including the Person Responsible work full time at the centre. The entire nursing and embryology team previously based at Holly House Hospital have relocated to the new premises. When the team were based at Holly House Hospital, patients were offered general anaesthetic for operative procedures. In the new premises, operative procedures will be performed under conscious sedation. The sedation will be administered by an anaesthetist assisted by a theatre department practitioner. The practitioner was present at the inspection and was able to describe the pre and post operative care of the patients. The inspection team were informed that the anaesthetist would not leave the premises until all patients who had received sedation had recovered and were discharged. In addition to the relocation of the entire nursing team several key members have been recruited to provide pre and post operative care. These include: • Operating Department Practitioner with 28 years experience and training in advanced life support. • Theatre Nurse • Recovery Nurse The Person Responsible assured the executive that a system is in place to ensure that appropriately registered staff are employed and that he had seen the registration certificates for the operating department practitioner, the theatre nurse and the recovery nurse. The Person Responsible will ensure that all patients are aware that operative procedures will be performed under conscious sedation not general anaesthetic and that they understand the term “deep sedation”. The electronic ‘IVF witnessing’ system has been installed on key pieces of equipment. This system will be thoroughly risk assessed prior to use. Initially the centre will manually witness in accordance with Directions.

Highlighted areas of firm compliance

No treatment services other than storage of gametes/embryos have been performed since the team relocated in December. The team have used the interim period to source and install equipment, update procedures, protocols and patient information, perform audits and attend training events such as:

- Basic life support
- Customer care
- Fire

Members of the nursing team will attend the Fertility nurse conference in February. Two members of the team will be attending a first aid course in February.

Areas for improvement

All protocols and procedures need to be reviewed and updated taking into account the relocation to new premises.

In circumstances when a patient produces a sample at home the accompanying form should ask for confirmation that the sample has not been tampered with.

The inspection team were informed that the clinical staff had theoretical training in Basic Life support and defibrillator training had been arranged.

The Person Responsible must ensure that staff are adequately trained in resuscitation techniques.

Points to consider/action for next inspection

Patient feedback

Training and Continuing Professional Development

The provision and quality of staff

Three consultants including the Person Responsible work full time at the centre.

The entire nursing and embryology team previously based at Holly House Hospital have relocated to the new premises.

In addition the Person Responsible has employed an experienced operating theatre practitioner, a theatre nurse and a recovery nurse.

The laboratory was considered to be adequately staffed with embryologists with suitable experience.

Topic 1

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **organisation**

A risk assessment to be performed regarding the number of treatment cycles which can be performed at the centre. Third party agreements to be completed. Completed risk assessments for all areas.	To be completed prior to treatment cycles being offered at the centre.
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **organisation** for the following reasons: As above

Topic 2

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **quality**

Action needed: A policy/procedure to be put in place regarding patient file management when they have been removed from the main filing system. A policy / procedure to be put in place regarding the use and response to the "Panic" button situated at reception	To be completed prior to treatment cycles being performed at the centre.
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **quality** for the following reasons: as above

Topic 3

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

Action needed: A policy / procedure to be put in place regarding the use and response to the "Panic" button situated at reception. Health and Safety/COSH notices to be displayed where required. Emergency trolley to be fully stocked and equipped. Assurances to be received for the Person Responsible that all equipment has been installed, serviced and validated.	To be completed prior to treatment cycles being performed at the centre.
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **premises** for the following reasons: As above

Topic 4

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information.**

Action needed: The telephone out of hours message to include a number for patients to call in the event of an emergency.	To be completed prior to treatment cycles being performed on the premises.
The following conditions apply:	

(c) The applicant does not yet meet the requirements for **information** for the following reasons: As above

Topic 5

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **laboratory and clinical practices**

Action needed: Laboratory protocols/ procedures to be updated taking into account the relocation to new premises.	To be completed prior to treatment cycles being performed on the premises.
The following conditions apply:	

(c)) The applicant does not yet meet the requirements for **laboratory and clinical practices** for the following reasons: As above.

Next Action

The Person Responsible and Registered Manager will inform the HFEA and HCC of progress made with outstanding issues.

Report to presented to licence committee 17th January 2008.

Health Care Commission registration will be granted when the assessor is satisfied that all issues have been addressed satisfactorily.

Summary of findings for Licence Committee
(If final visit before Application considered by LC)

Essex Fertility Centre has been licensed since 1992 and is a large sized clinic providing a variety of licensed treatments to self-funded and NHS patients.

The team at Essex Fertility Centre have moved to new custom built premises now known as "Hertfordshire and Essex Fertility Centre". The premises have been inspected by the HFEA and were issued with a licence to store gametes and embryos from 26th November 2007. This was agreed by Licence Committee on 29th October 2007.

Patients under the care of the fertility team have been informed of the relocation and have, where necessary consented to their stored gametes/ embryos being transferred to the new premises. The transfer of gametes / embryos to the new premises was completed on 28th November 2007.

The refurbishment of the new premises is now almost complete and the Person Responsible requests that the current licence to store be varied to include treatment. The appropriate fee and application have been received.

The entire fertility team apart from one part time administrator relocated to the new premises on 1st December 2007. No treatment services other than storage of gametes/embryos have been performed since this date and the team have used this time to update procedures, protocols and patient information, perform audits and attend training events.

The premises were seen to be pleasant and fit for purpose. Consideration had been taken for patient dignity and privacy.

Opening hours will be from 0900hrs - 1700hrs Monday to Friday and Saturday and Sunday as required.

They team expect to perform approximately 700 treatment cycles per year.

The PR has been in position since 1992 and is based at the centre full time. He has completed the Person Responsible assessment programme.

Several issues will need to be addressed prior to the team receiving registration from the Health Care Commission and HFEA licence for treatment.

It was considered by the inspection team that the centre team had worked with enthusiasm and dedication to achieve the pleasant, patient friendly environment in their new premises.

The Person Responsible and Registered Manager will provide assurances that all outstanding issues have been addressed prior to treatment services being commenced at the centre.

Appendix A: The inspection team and staff interviewed

The inspection team

Janet Kirkland	Chair, Inspector, HFEA
Dr Andrew Leonard	Inspector, HFEA
	Health Care Commission

Report compiled by: Janet Kirkland

Designation: Inspector

Date: 10TH January 2008

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number……..... ….

Name of PR……..…....

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Date of Inspection……..…....

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Date of Response……...….....

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Please state any actions you have taken or are planning to take following the inspection with time scales

I have read the inspection report and agree to meet the requirements of the report.

Signed…… ……

Name…… ……..…

Date…… ……....

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return this section of the report to:
Mrs Stephanie Sullivan
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF