Licence Renewal Inspection Report for Treatment and Storage Centres

Essex Fertility Centre
0030

Date of Inspection: 28th November 2006
Date of Licence Committee: 8th March 2007

CENTRE DETAILS

Centre Address	High Road, Buckhurst Hill, Essex 1G9 5HX
Telephone Number	020 8505 3315
Type of Inspection	Renewal
Person Responsible	Mr Michael Ah-Moye
Nominal Licensee	Andy Glew
Licence Number	LOO30/12/6
Inspector(s)	Janet Kirkland HFEA Lead inspector Parvez Quereshi HFEA generalist Sarah Hopper HFEA scientific inspector Stephen Lynch external scientific inspector
Fee Paid - date	awaiting invoice
Licence expiry date	30/06/07

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About the Inspection:
This inspection visit was carried out on 28th November and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between December 2005 and December 2006.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

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 Centre is located on two floors within a private hospital, Holly House. The reception, waiting room, administrative office, records store, embryology office, scanning room, 3 consulting rooms and 4 nursing rooms are located on the 1st floor of the hospital. The theatre, which is shared with other departments of the hospital and laboratory are located in the basement.

Opening hours are from 0900hrs -1700hrs Monday to Friday and Saturday and Sunday mornings.

The NL stated that there will be a potential increase in cycle numbers in the next year, perhaps around 200 extra cycles due to a new contract with Hampshire PCT. The PR is considering employing another consultant to accommodate this.

The PR has been in position since 1992 and is based at the centre full time.

Activities of the Centre

	Number of cycles 01/09/05-01/09/06	Treatments
Licensed treatment cycles	910	In Vitro Fertilisation IVF Intra Cytoplasmic Sperm Injection ICSI Zygote Intra Fallopian Transfer ZIFT Chemical Assisted Hatching GIFT with Donor Gametes Treatment with Donor Gametes
Donor Insemination	16	
Unlicensed treatments	120	
Research	X	
Storage	Yes	Storage of Sperm Storage of Embryos Storage of Testicular Tissue

*Data from HFEA Centrepede system 01/09/05-01/09/06

Summary for Licence Committee

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 patient areas are pleasant and well presented and patient feedback is primarily complimentary about the centre, team and treatments offered.

Success rates of treatments performed are above the national average.

The centre was assessed by the inspection team to require some improvement. The laboratory area was assessed as requiring significant improvement. The centre team are aware of the requirements and plan to refurbish the laboratories early in 2007 to comply with the EUTD Directive.

The inspection team considered that the Nominal Licensee had an extended role which appeared to encompass some of the responsibilities of the Person Responsible. As a result the Person Responsible was unaware of some of the details of activities at the centre.

The centre will be re-inspected following the refurbishment of the laboratory.

The inspection team support the renewal of the centres licence for a period of three years.

Risk Assessment

The last completed risk assessment was performed after the inspection. The risk score was 11%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation			X
2. Quality of the service		X	
3. Premises and Equipment			X
4. Information	X		
5. Laboratory and clinical processes		X	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
The storage of frozen gametes and embryos are not witnessed as per Directions D2004/4.	Ensure compliance with D2004/4 and review all witnessing practices.	Immediately
A log of three embryo transfer events has not been maintained by the PR.	Ensure compliance with D2004/21b: Each licensed centre must keep a summary log to include every treatment cycle involving the placing in a woman of three eggs or three embryos in the format (form nos. D2004/2A and B) set out in the Schedule to these Directions. This summary log shall be kept by the licensed centre and provided to or inspected by the Authority upon the Authority's request.	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
Currently only one embryologist is on the on-call rota to respond to low nitrogen alarms on the dewars. This could be considered as non-compliance with CH2(04)03 which requires adequate staffing and funding to allow the implementation of formal emergency procedures including "on-call'. The senior embryologist was asked to consider what would occur if his mobile was out of range and to risk assess this practice.	Risk assess this practice. Ensure compliance with CH(04)03.	Immediately

Recommendations	Time scale
Contingency measures that the PR has established with Bourn Hall should be documented.	1 month
Ensure that regular meetings are held within and between departments.	Immediately
All staff should be made aware of the HFEA definition of an incident.	Immediately
Training for the centre team should be formalised.	2 months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
At the time of the interim inspection the patient information sheet on blastocyst transfer did not include references and time ranges for the data presented, that the long-term effects of blastocyst culture are still unknown and there is a potential risk of multiple pregnancy with 2 blastocyst transfer. The PR should revise the patient information on blastocyst transfer and submit the revised documentation to the HFEA within one month.	The information submitted for the inspection did not include that the long term effects of blastocyst culture are still unknown.

Additional licence conditions and actions taken by centre since last inspection

C	**N/A**
A	**Complied Y/N**
C	**N/A**
A	**Complied Y/N**
C	**N/A**
A	**Complied Y/N**

Report of Inspection findings

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 is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
A daily diary is maintained which tracks each patient's progress during their treatment cycle. This was demonstrated to the inspectorate and considered to be excellent. Discussions with members of staff indicated that there is an honest, open, friendly culture within the team. A Quality Manager has been appointed and staff are working towards an ISO9001 quality management system. Payment of treatment fees is timely and the Centre is not listed on the HFEA debtors list.
Areas for improvement
The PR should be more involved in day to day running and communication within the centre. Evidence supporting this assertion includes the fact that the PIQ was completed by the senior embryologist and when questioned about compliance with last inspection recommendations the PR suggested that the inspectorate should consult the embryologist on this matter. The PR needs to ensure that he is fully informed of activities at his centre and of all HFEA communications and regulations. It was noted that the senior embryologist holds a great deal of responsibility within the centre. In addition to holding the position of quality manager, he is also in charge of incident handling and is currently the only embryologist on the on call rota. Team meetings are organised on a monthly basis. Minutes of these meetings were provided to the inspectorate. However, these documents indicated that there had been a lack of regular meetings in the past year.

Staff reported that they were aware of the incident reporting procedure. However some of the team were of the impression that most incidents were laboratory based. All staff should be aware of the HFEA definition of an incident; see Code of Practice Section 2.24: Adverse incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre.

The PR 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 agreement should be documented.

Executive recommendations for Licence Committee
The Person Responsible should consider the roles and responsibilities of the position. He should be aware of all communications with Regulatory Authorities and ensure that procedures and protocols comply with relevant Directions.

Areas not covered on this inspection
None

Evaluation
Significant improvements needed.

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:

- Live birth rates
- 'Welfare of the Child' arrangements
- 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
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
According to the HFEA success rate assessment (analysed data from 31st March 2002-1st April 2005) success rates with IVF/ICSI and FETs procedures were higher than the National Average in all age groups (below 35 years – 42 years).
Patient Questionnaire Analysis
The HFEA patient questionnaire data analysis (data gathered from July 2004-June 2006) indicates that patient satisfaction was above the National Average in all question areas; Clinic and Staff, Information, Counselling, Consent and Treatment, Drugs and Sharing Information. Five patient questionnaires have been received by the HFEA since the last inspection. Of these, one patient stated that they did not receive enough verbal/written information and did not have sufficient opportunity to ask questions. This patient also stated that they did not have a meeting where all options were discussed with them. Four of the questionnaires were complimentary about the service received; particular emphasis was given to the friendly nature of the staff.
Areas of firm compliance
Patient files were seen to be stored in locked cabinets in a room which is locked when not is use. The counsellor informed the inspectorate that counselling notes were stored separately. The inspectorate agreed that the patient information seen was of a good standard and appears to be easy to understand. Patient feedback is gathered by use of a questionnaire, which is currently under review, a patient forum on the website and a comments box which was seen to be located in the waiting room. The NL reported that there had only been one note retrieved from the box. The patients interviewed on the day of inspection expressed their satisfaction with the service

received and responses to the HFEA patient questionnaire were generally positive.

Counselling is offered to all patients and is free of charge. The counsellor reported that there is no waiting list. 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 therapeutic a maximum of three. All further counselling requirements are chargeable. The counsellor intends to attend the patient open meetings and team meetings.

Areas for improvement
To formalise the patient feedback system.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs) Donor selection

Evaluation
Some improvement needed

3. Premises and Equipment

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

Summary of findings from inspection:

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

Areas of firm compliance
The patient areas were considered to be fit for purpose by the inspectorate. All seven dewars were seen to be alarmed and locked.
Areas for improvement
Although the patient areas were seen to be satisfactory, it was noted that the laboratory space is restricted. When interviewed the embryologists supported this statement and stated that they felt that the number of cycles that could be accommodated at the centre was limited by the laboratory size. Currently there is only one flow hood in the laboratory which is not ideal considering the current workload. The senior embryologist stated that this, along with the limited space within the laboratory, will be addressed with the planned improvements which will be made to ensure compliance with the EUTD in April 2007. A low oxygen alarm system is present within the laboratory and although the alarm can be seen from the door it cannot be heard from outside. The inspectorate suggested that there should be a warning on the door of the embryology laboratory to warn persons not to enter in the event of the low oxygen alarm sounding. The Senior Embryologist stated that this system will be upgraded. Since the inspection the Senior Embryologist has informed the executive that it has not been upgraded as yet and a notice has not been placed on the door. He stated that he is confident in the safety of the current system. Dewars are stored in the laboratory which is accessed by a keypad lock. The laboratory can be entered through two separate doors and both can be securely locked. On the day of inspection one of the doors was open and the laboratory could be directly accessed from the public corridor. However, staff were in attendance and the senior embryologist assured the inspectorate that this door is closed and locked whenever the laboratory is unoccupied. The PR must ensure that the door is kept closed whenever unoccupied particularly as patients sit directly outside the laboratory whilst waiting for ET procedures. A protocol for response to the alarms has been produced and was considered satisfactory at the last interim inspection. However, only one embryologist is currently on the on-call rota to respond to the alarms. This could be considered as non-compliance with CH(04)03 which requires adequate staffing and funding to allow the implementation of formal emergency procedures including ‘on-call’. The senior embryologist was asked to consider what would occur if his mobile was out of range and to risk assess this practice. .

A documented system for monitoring equipment performance and safety has been designed but the use of this should be assessed/audited by the PR as the records actually showed that certain pieces of equipment had not been serviced at the expected intervals. It was noted that a number of pieces of laboratory equipment had not been subjected to Portable Appliance Testing (PAT) in the previous year. The Senior Embryologist stated that he plans to update the current system to one file per piece of equipment.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Significant improvements needed

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Six patient files were reviewed by the inspectorate. These were found to be in good order and evidenced that consents to disclosure, treatment and where applicable storage were in place.
Areas of firm compliance
Patient information seen was of a good standard and appears to be easy to understand. Patient records are stored in lockable cabinets within the administrative office. This office was seen to have restricted access to authorised members of staff through use of a key pad lock. Documents, patient information and protocols observed by the inspectorate were seen to be version controlled.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvements needed

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
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	7
HPC registered scientists	1
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	6

Summary of laboratory audit
An audit of all stored samples has not been conducted since the last inspection. The Senior Embryologist stated that this will be done once new tanks arrive. The HFEA should be informed of the outcome of this audit as soon as possible.
Summary of spot check of stored material
A spot check of stored material performed on the day of the inspection showed no discrepancies.
Areas of firm compliance
Audits of monthly pregnancy rates, fertilisation rates, freezing rates and average egg numbers are performed by the senior embryologist and were seen to be on display in the embryology office.
Areas for improvement
The standard of witnessing within the centre was not seen to be in accordance with HFEA guidance. An audit of patient records indicated that the movement of oocytes between culture dishes during fertilisation checks had not been witnessed. This is non-compliance with D2004/4. However, witnessing of this step has been recently introduced. Audit of records also showed that movement of embryos between dishes at time of oocytes stripping in preparation for ICSI procedures, movement from thaw dishes to culture dishes and then to ET dishes and during periods of extended culture are not witnessed. It was also noted that storage of frozen materials is not witnessed as per Directions D2004/47c. The PR was advised to review the witnessing practices within the laboratory and ensure that all movements of gametes and

embryos are witnessed appropriately. The PR was also reminded that witnessing should be documented in the patient records with a date and signatures of staff involved.

The PR could not provide a summary log of three embryo transfers performed as required by D2004/2.

Audits of clinic service should be extended to include audits within other departments, including administration and clinical practices.

Staff interviewed reported that they were happy with their opportunities for continuing professional development however training should be formalised. Currently there is no documented training plan for embryologists which indicates competency assessments. Apart from a hospital induction there is also no formal induction programme for staff working in the laboratory which takes into consideration the practices and protocols. According to the senior embryologist and the nurse manager a system of competency training is planned and a consultant is due to attend the centre to provide guidance on the set up of this system.

The counsellor informed the inspectorate that she is a member of BICA (British Infertility Counselling Association), Donor Conception Network and the British Fertility Society. She attends study days and has peer supervision. She reported that she funds her own continuing professional development.

The PR stated that medical staff have not been trained in the use of emergency equipment and that in the event of a resuscitation emergency the arrest team would be called. The Person Responsible also informed the inspectorate that the medical team had not received any mandatory training in the previous three to four years.

Although all members of the laboratory team that were interviewed stated that they felt capable of managing the current workload, the PR should consider the impact on staff of the planned increase in cycle numbers.

Executive recommendations for Licence Committee
Require compliance with D2004/2 and D2004/4.

Areas not covered on this inspection
Assessment of patients and donors

Evaluation
Some improvements needed.

Report compiled by:

Name……Janet Kirkland & Sarah Hopper…….

Designation……Inspector……..

Date……24th January 2007……

Appendix A: Centre Staff interviewed

Mr Michael Ah-Moye (PR) and 7 members of centre staff.

Appendix B: Licence history for previous 3 years

LICENSING HISTORY

Centre: Essex Fertility Centre

Centre number: 0030

Person responsible: Mr Michael Ah-Moye

Licensed for: IVF (with donor gametes), DI, GIFT with donor gametes, ICSI, storage of sperm (patient and donor), embryos and ZIFT.

2006

22/03/2006
The Committee noted that the centre has now complied with the additional conditions attached to its licence, and decided that the centre's licence should continue and the additional conditions be removed.

2005
Interim Inspection 15/12/2005

1) At the time of the interim inspection the patient information sheet on blastocyst transfer did not include references and time ranges for the data presented, that the long-term effects of blastocyst culture are still unknown and there is a potential risk of multiple pregnancy with 2 blastocyst transfer. The PR should revise its patient information on blastocyst transfer and submit the revised documentation to the HFEA within one month.
2) The Nominal Licence informed the inspection team that 2 blastocyst transfer is leading to a multiple birth rate of approximately 40%. To reduce the multiple birth rate the centre is move towards 1 blastocyst transfer in 2006.
3) The centre has compiled with all three previous conditions and recommendation.
4) The inspection team recommends the continuation of the centre's licence and supports the removal of the three additional conditions.

Licence Committee Meeting 23 March 2005
Conditions:

1) The Person Responsible must forward the results of the centre's audit of patient consent to the executive as soon as possible and in any event by the 31st July 2004
2) The Person Responsible must ensure that data given in publicity material is accompanied by the centre's own live birth rate per treatment cycle as verified by the HFEA and the national live birth rate per treatment cycle.
3) The Person Responsible must ensure that the practice of replacing oocytes at GIFT combined with embryos from IVF in the same treatment cycle must cease with

immediate effect.

2004

Interim Inspection 02/12/04

1) The centre does not have low nitrogen alarms fitted to the dewars as they awaiting completion of the refurbishment (paragraph 33).
2) The disposal of embryo laboratory sheet is not routinely completed and is difficult to follow. The centre should either ensure that the form is fully completed each time or redesign the laboratory sheet (paragraph 45).
3) Patient information for should be amended to include the long-term effects of blastocyst and make reference to the change in three embryo transfer (paragraph 68).
4) The centre has complied with all three conditions although not by the specified time period of the first additional condition.

Licence Committee of 9th February 2004

Conditions:

4) The Person Responsible must forward the results of the centre's audit of patient consent to the executive as soon as possible and in any event by the 31st July 2004
5) The Person Responsible must ensure that data given in publicity material is accompanied by the centre's own live birth rate per treatment cycle as verified by the HFEA and the national live birth rate per treatment cycle.
6) The Person Responsible must ensure that the practice of replacing oocytes at GIFT combined with embryos from IVF in the same treatment cycle must cease with immediate effect.

Recommendations:

1) While recognising that rebuilding work is planned within your centre the Committee recommend that low nitrogen-level alarms are fitted to all storage dewars as soon as possible.
2) In addition your centre should implement a policy to deal with an out-of-hours activation of the low oxygen-level alarm;
3) That your counselling protocols be updated by the present counsellor and the level of free counselling provision reviewed.

2003

Renewal Inspection 4th December

2002

There was no annual inspection in 2002

2001

Licence Committee 29th November

The Committee agreed to recognise Miss Corinna Warnecke as an ICSI practitioner.

Licence Committee 10th May

The Committee made 4 recommendations.

Renewal Inspection 3rd April

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……030……

Name of PR……Michae Ah-Moye FRCOG…….

Date of Inspection……28th November 2006……..

Date of Response……28th February 2007……

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

1. All transfers of eggs and embryos between dishes are witnessed now and the necessary changes have been made to the witnessing sheets.

2. An agreement has been drafted and is waiting approval between Bourn Hall and the Essex Fertility Centre. This should be ready for approval in the next few weeks.

3. Meetings are now regularly in place and follow the format as described in the management review policy attached.

4. We intend to hold a training seminar on HFEA Incidents, the HFEA incident inspectors will be invited to attend. We will include this into our yearly training schedule. HFEA incidents are risk assessed and discussed at the monthly team meetings.

5. Training programme is being formalized and will be ready in the time scale set.

6. The Blastocyst Information sheet has been modified to contain the risk statement as suggested and is attached

7. The quality management program which is currently being developed will address many of the issues highlighted in the report. Expected time for ISO 9001:200 completion – August 2007.

8. The laboratory is not fit for purpose, and this is being addressed by the relocation of Essex Fertility Centre to a purpose built Centre 7 miles from the present location. Expected relocation to occur in August 2007. The HFEA have been informed of this move.

9. Andy Glew is the only person on call for the alarm at the time of the inspection. However this has been increased to one other embryologist and the PR. All embryologists have mobile numbers and are available to receive calls in cases emergency.

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).

"The storage of frozen gametes and embryos are not witnessed as per Directions D2004/4"

The statement above may be misleading and could be perceived that we actually do not witness the whole procedure. **As from September 2007** the process of placing embryos and sperm into a tank location has been witnessed. All aspects of cryopreservation witnessing are observed, but the final placing in the tank location had not been routinely witnessed **prior to this date.**

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 Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

8 March 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Essex Fertility Centre, 0030
Licence Renewal

Members:
Clare Brown, Lay Member – Chair
Ruth Fasht, Lay Member
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Chris Barratt, Head of the Reproductive Biology and Genetics Research Group at the University of Birmingham

In Attendance:
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Claudia Lally, Committee Secretary

Observer:
Roger Neuberg

Conflicts 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:

- papers for Licence Committee (31 pages)
- no papers were tabled.

1. The papers for this item were presented by Janet Kirkland, HFEA Inspector. Ms Kirkland informed the Committee that this centre has good patient feedback and success rates which are above average. However, the inspection report identified a number of areas of improvement, specifically concerning the laboratory area. Following the inspection the Person Responsible informed the inspection team that the centre will be moving to a purpose built premises in August this year.

2. Ms Kirkland informed the Committee about the of areas of improvement identified at the inspection, and directed them to pages eight and nine of the inspection report. The centre has already addressed some of these, for example it has now implemented a witnessing protocol which is fully in line with Directions.

The centre has also implemented a policy of regular meetings and has modified its patient information to comply with suggestions from the inspection team.

3. Ms Kirkland informed the Committee that a response to the inspection had not been received by the Person Responsible in time to append it to the inspection report but had just been received this morning. She read this out to the Committee. This response affirmed that the Person Responsible considered himself to be in full control of the day to day running of the centre, and it also emphasised the significance of the forthcoming move of premises.

4. The Committee noted that the inspection report records that the storage of frozen gametes and embryos were not witnessed as required by Directions D2004/4. They further noted that this has now been put right by the centre.

5. The Committee noted that the centre does not keep a three embryo transfer log in contravention of Directions D2004/2. The Committee noted that this was not addressed in the response from the Person Responsible and agreed that the Person Responsible must ensure that this is done within two weeks of receipt of these minutes.

6. The Committee noted page 15 of the inspection report which states that laboratory space is restricted and asked Ms Kirkland to elaborate. Ms Kirkland replied that although this was not reported in the inspection report she felt that the problems associated with lack of space are exacerbated by the centre's practice of walking patients through the laboratory area in order to view their embryos under the microscope. The Committee agreed with Ms Kirkland that this practice should be brought to an end with immediate effect.

7. The Committee noted that there is no warning on the outside of the laboratory door about the danger associated with the low oxygen alarm sounding. The Committee agreed that this should be addressed by the centre immediately.

8. The Committee noted the low number of patient questionnaires which had been returned from patients at the centre. They agreed that the centre should be asked to stress to patients how important it is to return these questionnaires to the Authority.

9. The Committee agreed to renew the centre's licence for a period of one year, taking to account the fact that the centre plans to move premises in August, at which point a new licence would be required.

Signed……. … Date……..
Clare Brown (Chair)