Renewal Inspection Report

South East Fertility Clinic
0208

Date of Inspection: 22 October 2008
Date of Licence Committee: 12 January 2009

Centre Details

Person Responsible	Mr Michael Rimington
Nominal Licensee	Mr Mark Wilcox
Centre name	South East Fertility Clinic
Centre number	0208
Centre address	Amberely House 9 Queens Road Royal Tunbridge Wells Kent TN4 9LL
Type of inspection	Renewal
Inspector(s)	Paula Nolan Sarah Hopper Janet Kirkland (external adviser)
Fee paid	Renewal fee paid
Licence expiry date	30 April 2009
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 22 October 2008.

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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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

South East Fertility Clinic (centre 0208) was originally located within the Nuffield hospital in Tunbridge Wells. An application was received in 2006 to close the unit from within the Nuffield and move premises to its current location. The application for new premises was granted in November 2006 and a three year licence was awarded. The centre has been in its current location since January 2007.

South East Fertility Clinic is registered with the Healthcare Commission and underwent its last self-assessment in March 2008.

The centre provides treatment with donated eggs, accepts speculative sperm donors (does not actively recruit).

The centre treats private patients and is anticipating treating NHS patients by the end of the year.

Opening hours at the centre are: Monday – Friday 09.00 – 17.00 and Saturday 09.00 – 12.00.

The Person Responsible (PR) has completed the HFEA Person Responsible Entry Programme. He is registered with the General Medical Council (GMC) and is on the Obstetric and Gynaecology specialist register.

It should be noted that the Laboratory Manager, Steven Lynch, has been recruited by the HFEA Executive as an external inspector.

Activities of the Centre[1] for the time period from 1 July 2007 to 31 July 2008.

In vitro fertilisation (IVF)	144
Intracytoplasmic sperm injection (ICSI)	152
Frozen embryo transfer (FET)	75
Intra uterine insemination (IUI)	117[2]
Donor Insemination (DI)	64
Research	No
Storage gametes/embryos	Yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

[2] Based on treatments between 5 July 2007 and 31 December 2007.

Summary for Licence Committee

The South East Fertility Clinic is a moderately small unit providing 552 licensed treatment cycles per year.

There have been no significant changes in the centre in terms of activity, patient demographics and premises since the last inspection in May 2007. However the centre is anticipating treating NHS patients by the end of the year.

The inspectorate agreed that no improvements, with relation to the requirements of the Code of Practice, are required in the areas of quality of service and information. Some improvements are recommended in the areas of organisation, premises and equipment and laboratory and clinical processes. In particular, improvements should be considered relating to the following aspects of the centre's practice:

- Payment of fees;
- Audit reports to contain action plan and date of review;
- All incidents to be reported via the HFEA incident reporting system;
- Validation of key processes and procedures;
- Competency assessments completed for all staff.

The inspection team supports the continuation of the centre's licence without additional conditions.

Evaluations from the inspection

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

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
For the year up to July 2008, the average time taken to pay	The Person Responsible should review the arrangements for payment of invoices and ensure that there are	At the centre's discretion. Progress to be monitored at

HFEA invoices was 54 days. This is potentially a breach of standard licence condition A.16.3.	no barriers to the prompt payment of invoices.	the time of the next inspection.
Some of the audit reports that had identified non-conformities did not have an agreed action plan or date for the corrective actions to be put in place.	To comply with Standard 9.2.5. of the Code of Practice the PR should ensure that records of audits are kept that include: (i) the processes, areas or items audited (ii) any non conformities found (iii) recommendations and time scale for action (iv) record of action taken and subsequent verification of effectiveness.	By 22 January 2009.
Not all incidents logged in the centre's incident log had been reported to the HFEA.	The centre must report all adverse incidents (which includes serious adverse events and serious adverse reactions), and all near misses to the HFEA to comply with D.2007/3. The PR should report the incidents identified by the inspectorate during the inspection via the HFEA incident alert system.	Immediately.
Validation of key processes and procedures has not yet been fully established.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes and equipment considered to be most likely to impact on the quality of the service and ensure compliance with Licence Conditions 11.11, 8.11 and 10.13 and Code of Practice Standards 7.8.3, S.6.4.2 and S.6.4.2.	Progress to be monitored in the course of the next inspection.
Not all members of staff have had their competency to perform designated tasks assessed. This is potentially non compliant with	The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System and re-training undertaken when required. The PR should also ensure compliance with	A programme of assessment should be developed immediately and the timeline for completion of the assessment programme should be submitted to the HFEA by

standards S.6.2.7 (a). This breach was also noted at the time of the previous inspection.	Code of Practice Guidance 1.3.1 which requires all nurses to be able to provide evidence of competency in the duties performed either by certification of a recognised qualification or by written testimonial by another suitable qualified and competent person in that discipline/function (e.g. ultrasound, embryo transfer, IUI, egg collection, etc.)	22 December 2008. Full implementation of the proposed assessment programme reported to the HFEA.

Non-Compliance

Area for improvement	Action required	Time scale
The witnessing sheet does not provide an opportunity to record the time the witnessing took place.	It was suggested by the inspectorate that the laboratory sheet be updated to include the time of witnessing thus ensuring compliance with Code of Practice guidance 13.2.1.	Within the next three months.

Recommendations

Area for improvement	Action required	Time scale
During inspection it was mentioned by the Laboratory Manager that there is not enough spare capacity within the storage dewars to provide for relocation of gametes/embryos should one of the dewars fail and that a spare dewar is needed.	The PR should assess the risks associated with the current storage facilities to evaluate whether a spare dewar is needed.	At the PR's discretion.
The counsellor stores counselling notes and sees patients in her home.	The PR should visit the premises and carry out a risk assessment to ensure that the notes are stored securely, facilities are provided in private and confidential surroundings.	At the PR's discretion.
As the centre is anticipating accepting NHS patients the PR should consider assessing how many treatment cycles can safely be accommodated by the centre.	The assessment should consider the centre's premises, staffing levels and skill mix of staff members: activity should be adjusted according to the findings of the assessment.	At the PR's discretion.

Changes/ improvements since last inspection

Recommendations	Action Taken
Validation of processes and procedures as required in S 7.8.3 of the Code of Practice have not been conducted.	Ongoing.
Air quality testing was last performed within the unit prior to the commencement of licensed treatments in January 2007.	Air quality testing was carried out in January 2008 and was satisfactory A regular programme for testing will be devised by the embryologists.
It was noted that the three-embryo transfer log only contained the age of the woman as the reason. It was recommended that additional factors should also be included as evidence that age was not the only reason for three-embryo transfers being performed.	The three-embryo transfer log now notes additional factors.
A formal documented contingency plan should be formalised and documented for any possibility that the whole unit be inaccessible.	A formal documented contingency plan is in place with Sussex Downs Fertility Centre (0015).
It was noted that although competencies have been documented for laboratory staff, these are still currently in development for other departments such as nursing. It was recommended that these be finalised and implemented for all departments.	Competencies for nursing staff have been established but it remains the case that not all members of staff have had their competency to perform designated tasks assessed.
Plant equipment used for the laboratory and treatment room is housed at the back of the unit. It was noted that this is unguarded and could therefore potentially be accessible to vandals. It is recommended that the centre risk assess the potential risks associated with the equipment being vandalised and its effect on the running of the business.	A 'cage' to safeguard the plant equipment has been designed and is in place. This area has also been gated off to prevent unauthorised access.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without additional conditions.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Documentation submitted for inspection, including an organisational chart showing key responsibilities and lines of accountability was reviewed by the inspection team and was considered to be appropriate. With two exceptions, the Person Responsible (PR) has implemented changes as recommended in the report of the previous inspection. The premises appeared suitably equipped and the PR reported that he is confident that the unit has sufficient staff with relevant expertise. A number of audits have been conducted by the clinical team. These include audits of infection control procedures and nurse consultation and scanning. Copies of the audit reports were provided during the inspection and included the identification of non-conformities found during the audit. Processes are in place for the identification, notification and investigation of incidents. The centre's complaints log was reviewed by the inspection team and evidence of actions taken to resolve complaints were noted. Patients are provided with an out of hours emergency phone number. The unit also has a service level agreement with the local NHS hospital's accident and emergency department. A formal contingency arrangement plan is in place with Sussex Downs Fertility Centre (0015). Third party agreements are in place and were made available to the inspection team to review. A sample of agreements were reviewed and were compliant with HFEA guidelines. Minutes of weekly multi-disciplinary team meetings held to discuss practice related issues

were seen during the inspection. Issues such as nursing, embryology and clinical updates as well as patient complaints and compliments were discussed.

Areas for improvement

Some of the audit reports that had identified non-conformities did not have an agreed action plan or date for the corrective actions to be put in place. (Code of Practice (CoP) Standard 9.2.5.)

While processes are in place to identify incidents and to investigate/resolve them not all incidents logged in the centre's incident log had been reported to the HFEA. (D 2007/3)

The average time for the payment of treatment fees to the Authority is 54 days. This is potentially a breach of standard licence condition A.16.3. which requires payment within 28 working days.

Areas for consideration

One nurse interviewed explained that in the previous week due to staff holidays and sickness the unit had been short of nursing staff. Clinical duties were unaffected but the telephones were left unanswered. As the centre is anticipating accepting NHS patients the PR should consider assessing how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, staffing levels and skill mix of staff members: activity should be adjusted according to the findings of the assessment.

Executive recommendations for Licence Committee

To comply with Standard 9.2.5. of the Code of Practice the PR should ensure that records of audits are kept that include:
(i) the processes, areas or items audited;
(ii) any non conformities found;
(iii) recommendations and time scale for action;
(iv) record of action taken and subsequent and verification of effectiveness.

The centre must report all adverse incidents (which includes serious adverse events and serious adverse reactions), and all near misses to the HFEA within 12 working hours to comply with D.2007/3. The Person Responsible should ensure all staff receive adequate training to comply with this direction.

The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices as per Licence Condition A 16.3.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from the 1 January 2004 to 31 December 2007 the centre's outcomes were in line with the national average.
Areas of firm compliance
The centre has an electronic quality management system in place and has assigned a quality manager. The centre was certified as ISO 9000:2001 compliant in 2006. Regular meetings with staff are held to discuss quality issues and clinical governance. Evidence of these meetings was provided to inspectors in the form of minutes taken from the meetings. Quality performance indicators have been established and evidence of monitoring clinical and laboratory practices was provided in the course of the inspection. Eleven patient questionnaires were returned to the HFEA: seven respondents made positive comments about the treatment they received. There is a suggestion box in the waiting area so that patients' views on the quality of service provided to them can be obtained. Any suggestions made are discussed by staff and where possible improvements are made. Evidence of discussion of patient feedback was recorded in minutes of multi disciplinary team meetings. It was noted by the inspectorate that there is an effective document control procedure in place. This was evident from the documents reviewed by the inspection team and discussions held with the staff.
Areas for improvement
None.
Areas for consideration
None.

Executive recommendations for Licence Committee
None.
Evaluation
No improvements required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. The areas seen during the visit appeared to be clean and well presented. The counsellor was not available for interview on the day of inspection. The PR confirmed that a consulting room within the centre can be made available for counselling sessions although it was noted that the counsellor can see some patients at her own home if this is preferred. The PR stated that all counselling notes are kept in secure storage at the counsellor's home. The emergency trolley located in the centre was checked and was found to be well maintained. It is checked on a daily basis and entries were seen to be made in an appropriate log. The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment. Maintenance contracts are in place for key pieces of equipment and evidence of this was seen during the visit. Evidence of air quality monitoring in all relevant areas was provided in the course of the inspection. Air quality was last monitored in October 2008: background air quality was assessed as grade D and air quality in processing areas was assessed as grade B in accordance with HFEA requirements. The centre's current cryostore facilities appeared to be adequate for the volume of work being conducted. The cryostore is fitted with a low oxygen level monitor. All dewars are alarmed and the centre has a procedure in place for responding to alarms. Logs of monitoring activities carried out in the laboratory are kept and these were seen by the inspection team and considered to be well organised. Procedures have been implemented to ensure the traceability of consumables that come into contact with gametes and embryos.

Staff facilities including a changing area, toilet/shower and lockers along with kitchen for staff use were considered appropriate by the inspectorate.

The nursing office contains the current patient notes in locked filling cabinets. The basement of the building contains archived patient notes (securely).

Areas for improvement

The Head of Laboratory stated that there is not enough spare capacity within the storage dewars to provide for relocation of gametes/embryos should one of the dewars fail and that a spare dewar is needed.

Air quality is checked on a quarterly basis however this process has not been validated to support testing at these intervals. The PR stated that validation of processes has begun and the Head of Laboratory confirmed that he has started to add references to the standard operating procedures to support their methodology.

Areas for consideration

As the counsellor stores counselling notes and sees patients in her home the PR should visit the premises and carry out a risk assessment to ensure:

- all counselling notes are held securely and confidentially (CoP A.10.31, S.7.2, G.10.31, G.7.2, G.7.4)
- the facilities are provided in quite, comfortable, private and confidential surroundings (CoP G.7.2, G.7.4 and S.6.3.5, G.1.4.1.)

Executive recommendations for Licence Committee

The PR should assess the risks associated with the current storage facilities to evaluate whether a spare dewar is needed to comply with Code of Practice Standard 6.3.8.

It is recommended that the unit continues its programme of validation of processes and equipment thus ensuring compliance with Licence Conditions 11.11, 8.11 and 10.13 and Code of Practice Standards 7.8.3, S.6.4.2 and S.6.4.2.

Evaluation

Some improvements required.

Areas not covered on this inspection

Al areas covered.

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Audit of records
An audit was conducted on ten sets of patient notes. All sets of notes contained the relevant consent forms however three "consent to disclosure" forms were incorrectly completed. The PR confirmed that at present the centre only treats private patients therefore information to third parties such as GPs would not be disclosed. A review of the communication section of the notes confirmed that information had not been sent out to third parties. The PR stated that a new policy will be drawn up for NHS patients regarding consent and disclosure to third parties. One posthumous treatment consent form has not been correctly completed. The PR explained that he would ask the patient back to complete the correct consent information. The PR stated that he would take action to ensure that all consent forms are completed fully and without ambiguity in the future.
Areas of firm compliance
Information provided to patients in the form of a booklet was made available to the inspectorate and was considered appropriate. Discussions held with staff confirmed that the centre has appropriate procedures in place to ensure that proper account is taken of the welfare of the child when considering treatment. The PR confirmed that they have a procedure for responding to patient requests for access to their health records.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
The PR should ensure staff are trained to obtain consent and that it is recorded in accordance with relevant directions issued by the HFEA to comply with Standard 7.5.6.

Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	1.25
NMC registered nurses	3.5
Non NMC registered clinical staff	0.8
HPC registered scientists	2.4
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	4.7
Counsellors	1

Summary of laboratory audit
A summary of the findings of an audit of all stored material was submitted prior to the inspection. No discrepancies were reported in the audit of sperm samples. Of the remaining dewars containing embryos, 14 discrepancies were noted in the audit report. The actions taken to remedy and correct the discrepancies were recorded.
Summary of spot check of stored material
In a spot check audit carried out on the day of inspection, two embryos and two sperm samples were tracked from freeze record to dewar. No discrepancies were noted. One embryo was tracked from dewar to freeze record. Although a freeze record was in place and contained the correct information about storage location etc, the general storage index had not been updated so it was initially difficult to find the freeze record: this was discussed and resolved during the inspection. One sperm sample was tracked from dewar to freeze record: no discrepancies were noted.

In addition to the spot check the inspectorate requested to see a log of all embryos and sperm that they have in storage. The information provided indicated that no gametes or embryos are currently in storage beyond their consented period.

Areas of firm compliance

There is an appropriate induction program in place for new employees. Evidence was provided of a training and induction plan for the newest member of staff.

Comprehensive training logs are held on the centre's secure server. Evidence was provided of a training log which contained all continuous professional development training attended along with evidence of mandatory training attended.

There are policies in place for assessment of patients seeking treatments and for screening of patients. This was evident from the documentation submitted for inspection and discussion held with staff.

The three – embryo transfer log provided evidence that no three embryo transfers had been conducted on women under the age of 40.

During the inspection evidence was provided to ensure that materials and equipment which come into contact with gametes and embryos are traceable from procurement to disposal.

The PR confirmed that the Counsellor is a member of the British Infertility Counselling Association. There is no waiting list for counselling and appointments are made directly or by referral from another member of the team. The counselling audit supplied indicates that the uptake of counselling has increased by 9% for implications (donor) and 11% for implications (recipient) compared to the 2007 audit.

The PR explained that the counsellor attends the regular team meeting. Minutes of previous team meeting supported this information.

Areas for improvement

Although competencies have now been developed for the nursing staff they have not had the opportunity to complete them. This breach was also noted at the time of the previous inspection.

Not all of the witnessing checks included the time this was performed. Omissions were noted in two sets of records in relation to the documentation of witnessing. (CoP G 13.1.1a.)

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR must ensure that staff are competent to perform the required procedures and work to current versions of these procedures to comply with Standard 7.8.3 of the Code of Practice.

It was suggested by the inspectorate that the laboratory sheet is updated to include the time of witnessing thus ensuring compliance with Guidance 13.2.1. of the Code of Practice.
Evaluation
Some improvements required.
Areas not covered on this inspection
All areas covered.

Report compiled by:

Name – Paula Nolan

Designation – Inspector

Date – 18 November 2008

Appendix A: Centre staff interviewed

Mr Michael Rimington (PR) and 5 members of staff.

Appendix B: Licence history for previous 3 years

13 February 2008

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this centre has only been in its current premises since January 2007. Following the inspection the centre has a risk score of 5%, in the low range.

2. Mr Qureshi drew the attention of the Committee to the response to the inspection report by the Person Responsible, appended to the report at page 21. This response demonstrates that most of the concerns of the inspection team have now been addressed or are in the process of being addressed.

3. The Committee noted and endorsed most of the recommendations of the inspection team. However, they did not agree with the recommendation that reasons should be recorded for all three embryo transfers to women over 40 years of age.

4. The Committee agreed that the centre's licence should continue with no additional conditions.

2 May 2007
South East Fertility Unit, 0208
Licence Variation pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

1. The papers for this item were presented by Tony Knox, HFEA Inspector. Mr Knox informed the Committee that the centre's risk rating, reflecting the degree of compliance with EUTD requirements, was 2%, in the low range.

2. Mr Knox informed the Committee that the centre is close to full compliance with EUTD requirements but is still working on data management protocols.

3. The Committee noted that the centre is working towards full compliance with the

requirements of the EUTD and that progress will be assessed at the next inspection visit to the centre.

4. The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0208

Name of PR Michael Rimington

Date of Inspection 22 October 2008

Date of Response 5 December 2008

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

Signed

Name Michael Rimington

Date 5 December 2008

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

None

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

It should be noted that no request for late settlement of the account has ever been made from the HFEA to date in this respect. We would prefer this inference of poor payment to be deleted from the published inspection report.

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

Payment of Fees
We have never been sent a reminder for payment while at Amberley House (since January 2007). We have routinely been paying the fees in our monthly cheque run and did not know there was a problem with this until you raised the matter. Further to our inspection this has been altered with immediate effect to make a BACS payment as soon as the invoice is received.
Timescale: Immediate

Audit
Nurse co-ordinator to amend existing 2008 audit documentation to include review period and owner and corrective action date. Audit programme to be co-ordinated under ISO objective number 1 for 2009.
Timescale: 22 January 2009

Incidents
Incidents have been reported to the HFEA as requested. In future all incidents will be forwarded.
Timescale: Immediate

Validation
Regarding validation processes, the ACE guidelines and validation process is to be published in January 2009 and will be adopted by SEFC under the guidance of the Laboratory Manager and Quality Manager.
Timescale: 31 March 2009

Competencies
The Nurse Co-ordinator has scheduled the final nurse competencies meetings and these will be complete by the end of December 2008.
Timescale: 22 December 2008

Witnessing
The laboratory witnessing sheets will be updated to include the time as well as the date.
Timescale: Immediate

Storage Dewars
We are currently looking into the purchase of an extra storage dewar for the laboratory. This has been discussed by the Medical Advisory Committee and will be resolved in the New Year.
Timescale: Ongoing

Counsellor's notes
The PR will visit the counsellor's premises to assess the storage of notes for SEFC patients receiving counselling to ensure that it is appropriate.
Timescale: 31 January 2009

Policy for Consent to Disclosure

The policy for consent to disclosure has been created for NHS patients to ensure written permission is given to write to their family doctor.
Timescale: Immediate

Audit of Records
The inspection audit revealed one posthumous consent form to be incomplete. The couple have been contacted and the form corrected.
Timescale: Immediate

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

12 January 2009
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

South East Fertility Centre, 0208
Licence Renewal

Members of the Committee:	In Attendance:
David Archard, Lay Member – Chair	Claudia Lally, Committee Secretary
Sally Cheshire, Lay Member Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Providing Legal Advice to the Committee:
Hossam Abdulla, Director, Lister Fertility Clinic	Graham Miles, Morgan Cole Solicitors

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:

- papers for Licence Committee (34 pages)
- no papers were tabled.

1. The papers for this item were presented by Paula Nolan, HFEA Inspector. Ms Nolan informed the Committee that this centre has been at its current location since January 2007; the centre currently treats private patients and planned to take on NHS patients at the beginning of 2009. Ms Nolan reported that the renewal inspection to this centre took place on 22 October 2008. A number of areas for improvement were identified:

    - timely payment of fees
    - audit procedure
    - reporting of incidents
    - validation of key processes and procedures
    - assessment of competencies, and
    - witnessing procedure.

2. Ms Nolan directed the Committee to the response to the report by the Person Responsible (appended to the report at pages 24 to 25). This response set out the actions which are being taken to address the findings of the report. The response makes it clear that most of the areas for improvement have already been addressed. Ms Nolan also informed the Committee that areas for improvement identified at the previous inspection of the centre have all now been addressed.

The Committee's Decision

3. The Committee noted the findings of the report and welcomed the fact that the response by the Person Responsible indicated his intention to comply with the all recommendations of the inspection team. The Committee noted that an interim inspection to the centre is due in the next inspection year and asked that, as for all centres, the Inspectorate look for evidence of compliance with professional guidelines, particularly in relation to counselling.

4. The Committee noted the action taken by the Person Responsible in connection with nurse competences. The Committee recommended that this include training on the consent process, particularly in relation to the disclosure of information to third parties. The Committee noted that consent to disclosure to third parties should not differentiate between different categories of patients, i.e. private and NHS.

5. The Committee endorsed the suggestion at page 11 of the inspection report that if the centre's workload increases significantly following the commencement of treating NHS patients, the Person Responsible should carry out a risk assessment to determine the numbers of cycles which could be safely accommodated with current resources.

6. The Committee agreed to renew the centre's licence for a period of five years.

Signed……. … Date……..
David Archard (Chair)