Interim Inspection Report

Date of Inspection: 10 November 2010
Length of inspection: 7 hours
Inspectors: Paula Nolan, Andrew Leonard,
Rosetta Wotton (Observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 22 October 2008 and 21 January 2011.

Date of Executive Licensing Panel: 21 January 2011

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim 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 Authority's Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	South East Fertility Centre
Centre Number	0208
Licence Number	L0208/7/b
Centre Address	Amberely House, 9 Queens Road Royal Tunbridge Wells TN4 9LL
Telephone Number	01892 614110
Person Responsible	Mr Michael Rimington
Licence Holder	Mr Mark Wilcox
Date Licence issued	01/05/2009
Licence expiry date	30/04/2014
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspection team considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including 1major area of non-compliance and 3 other areas of non-compliance.

Since the inspection visit the PR has provided information and evidence that in the view of the inspection team demonstrates that the centre has implemented all of the recommendations made in relation to these non compliances. The recommendations made related to the following aspects of practice:

- Complete Welfare of the Child assessments.
- Document the procedure for responding to patient or partner withdrawal of consent to parenthood.
- Document the procedure for the withdrawal of consent by one gamete provider to the continued storage of embryos ("cooling off period").
- Review procedures for the screening of donors to ensure that donors of gametes and embryos are screened in accordance with current professional body guidelines.

Details of Inspection findings

Brief description of the centre and its licensing history:

South East Fertility Clinic (centre 0208) has been licensed by the HFEA since 2004 and has a history of good compliance. The centre offers a comprehensive range of assisted reproductive therapies to both self funded and NHS contracted patients.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1/08/2009 – 31/07/2010*
In vitro fertilisation (IVF)	233
Intracytoplasmic sperm injection (ICSI)	239
Frozen embryo transfer (FET)	87
Donor intra uterine insemination (DI)	63
Partner intra uterine insemination (IUI)	190 (in the calendar year ending 2009)

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*These data were extracted from the HFEA register for the period 1/08/2009 – 31/07/2010. 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.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. Before treatment is offered the centre provides the person seeking treatment, and their partner (if applicable) with a personalised costed treatment plan. The PR provided examples of treatment plans that included all elements of the treatment proposed (including blood tests, scans and cost of drugs). Relevant staff have undergone training in seeking consent to legal parenthood where applicable for those being treated with donor gametes or embryos. Staff interviewed were able to demonstrate an understanding of the requirements of legal parenthood legislation. The centre has a procedure in place for consent to legal parenthood to ensure the appropriate consent forms are completed having been fully explained to patients.
What they could do better. The centre has not established documented procedures to guide the process in the event that consent to legal parenthood is withdrawn or varied by either party and to ensure that no treatment is provided to a woman prior to her being informed of the change as required by standard licence conditions T64 and T65.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. The centre seeks consent to the disclosure of patient information held on the HFEA register, to researchers. An audit of four sets of patient records was conducted on inspection. HFEA consent to disclosure had been completed appropriately in each record seen. During discussions staff were able to demonstrate knowledge of the recent changes to the statutory storage periods permissible for gametes and embryos. The centre's database of stored embryos was reviewed during the inspection and indicated that all embryos stored have effective consent in place. The centre operates a 'bring-forward' system to ensure sufficient advance notice of the end of the statutory storage period (or shorter if specified by the gamete provider's consent) to prevent the storage of licensed material beyond the permitted period.
What they could do better. The centre does not have a standard operating procedure (SOP) guiding

the procedure for the withdrawal of consent for embryo storage which includes the provision of a 12 month “cooling off’ period and dispute resolution processes. (Standard licence condition T33 (b))

Multiple births

What the centre does well.

The PR reported an overall multiple clinical pregnancy rate at the time of inspection of 22%.

In accordance with General Directions 0003 the centre has a multiple birth minimisation strategy and maintains a summary log of cases in which multiple embryos have been transferred to patients who meets the criteria for elective single embryo transfer (eSET). The strategy was seen to include guidance on:

- how the centre identifies suitable cases for eSET, including embryo assessment and patient selection criteria; (General Direction 0003 5(a)) and
- how the centre aims to reduce their multiple birth rate to ensure that the 2010 target of 20% or below is achieved. (General Direction 0003 5(b)).

Where multiple embryos were transferred to patients who met the criteria for eSET, the reasons for this have been recorded in the patient notes.

The centre has carried out regular audits and evaluation of the progress and effectiveness of their strategy. Evidence of this was seen in the minutes of team meetings.

The PR provided the inspection team with a summary log of all treatments in which three embryos have been placed in a woman. The age, (all above 40 years) and the clinical rationale for transferring three embryos was seen to have been recorded in the patient record on each occasion.

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

All critical equipment and processes have been identified and validated in compliance with standard licence conditions T24 and T72. The scientific inspector sampled the validation reports and noted that the Association of Clinical Embryologists’ validation templates have been used.

What they could do better.

Nothing noted at the time of inspection.

Witnessing

What the centre does well.

An audit of four sets of patient records confirmed that all witnessing steps are recorded appropriately by practitioner and witness. The inspection team were satisfied that the identification of samples and the patients/donors to whom they relate is witnessed by two members of staff contemporaneously at all critical points of the clinical and laboratory process (Standard licence condition T71).

Staff involved in carrying out witnessing provided documented evidence of the assessment of their competence in carrying out witnessing. (Standards licence Condition T15 (a)).

What they could do better.

Nothing noted at the time of inspection.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Four sets of patient records pertaining to gamete donors (egg and sperm donors) were audited during the course of the inspection. This sample of records provided evidence that:

- donors are selected on the basis of their health and medical history, provided in a questionnaire and through a personal interview (Standard licence condition T52);
- donors are selected in accordance with the screening requirements of standard licence condition T52;
- the laboratory tests required by standard licence condition T52 have been carried out by a qualified laboratory which has been accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (Standard licence condition T53);
- donor sperm is being quarantined for a minimum of 180 days, after which repeat testing is performed (Standard licence condition T53 (c)).

The donor screening procedures are supported by a documented SOP and a checklist which is completed for every donor. The checklist includes all of the screening tests that must be conducted and copies of these checklists were seen to be included in all donor records audited.

All reimbursements are logged on a donor payment sheet, along with the rationale for the payments. These arrangements are compliant with

General Directions 0001. Discussions with staff indicated that the recipients of donor gametes are advised about the importance of informing any resulting child at an early age that the child results from the use of donated gametes. (Standard licence condition T63a).
What they could do better. Donors are not being screened in accordance with professional guidance. The donor records reviewed on inspection indicated that donors had not been assessed regarding transmissible spongiform encephalopathies nor had sperm donors undergone a physical examination[1].

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. As the centre offers a full range of treatment services this theme was not relevant at this inspection.
What they could do better. Analysis of the centre's self assessment questionnaire indicated that Welfare of the Child procedures needed to be reviewed during the inspection visit. This issue is discussed in Section 3 – areas of concern.

Embryo testing (if applicable)
What the centre does well. Not applicable for this centre.
What they could do better. Not applicable for this centre.

[1] UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008). Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society, Royal College of Obstetricians and Gynaecologists. December 2008 *Human Fertility* 11 (4): 201-210

2. Changes / improvements since the last inspection on 22/10/ 2008

Area for improvement	Action required	Action taken as evidence during this inspection
For the year up to July 2008, the average time taken to pay HFEA invoices was 54 days.	The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	The HFEA finance department reported that the centre has been paying invoices within the 28 days payment terms. No further action is required.
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.	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) a record of action taken and subsequent verification of effectiveness.	On inspection the Quality Manager provided evidence of action plans, dates for corrective actions to be put in place and follow up dates for re-audit if required. No further action is required.
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.	The centre's incident log was reviewed at inspection. All incidents logged were seen to have been reported to the HFEA and corresponded with the records held by the HFEA. No further action is required.
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.	On inspection it was noted that the validation of processes is now complete. No further action is required.

Area for improvement	Action required	Action taken as evidence during this inspection
Not all members of staff have had their competency to perform designated tasks assessed.	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.	Evidence of competence assessments for information provision, obtaining consent and consent to disclosure of information was provided. No further action is required.
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.	Witnessing records were seen to record the time at which each witnessing step was performed. No further action is required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
Guidance Note 23: The quality management system The SAQ states that quality indicators/objectives have not been established for all activities.	The Quality Manager explained that since the SAQ was completed in January 2010 the centre has set quality indicators. The Quality Manager provided evidence that quality indicators have been established for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence including counselling, provision of information, consent and witnessing.	No further action required.
Guidance Note 8: Welfare of the Child The SAQ states that the centre has not established quality indicators or objectives relevant to the assessment of the welfare of the child. Nor have welfare of the child	The Quality Manager explained that since the SAQ was completed in January 2010, the centre has set quality indicators and provided evidence that welfare of the child procedures are audited against compliance with the approved protocols. On the day of inspection an audit of four sets of patient records indicated that welfare of the child assessments	Further action required (see next section).

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
procedures been audited against compliance with the approved protocols in the last two years.	were incomplete in three sets of records. One set of records indicated that the patient had re-married but a new welfare of the child assessment had not been completed.	
Guidance Note 3: Counselling The centre's counsellor was not available at the previous renewal inspection. Therefore the Licence Committee asked that the inspectorate look for evidence of compliance with professional guidelines, particularly in relation to counselling at the following interim inspection.	The self assessment questionnaire submitted prior to inspection confirms that the centre's counsellor follows counselling SOPs (copies of counselling SOPS were provided during the course of the inspection) and that quality indicators have been set for counselling.	No further action required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None noted at the time of inspection.					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
An audit of four sets of patient records indicated that welfare of the child assessments were incomplete in three sets of records. One set of records indicated that the patient had re-married but a new welfare of the child assessment had not been completed.	Standard licence condition T56 Guidance Note 8.6	The PR must ensure welfare of the child assessments are correctly completed for these three patients. The centre should repeat the assessment if: (a) the centre has been out of contact with the patient for two years or more (b) the patient has a new partner The centre should undertake a full audit of medical records for patients currently undergoing treatment to	Immediately The detailed action plan should be submitted	See 'Additional Information' below Audit and action plan complete.	To be followed up with PR on 31 March 2011.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
		ensure that the welfare of the child assessment is correctly completed. The PR should submit a detailed action plan outlining the scale of the audit and the anticipated completion date. The completed audit report should include a summary of the amount of errors found and corrective actions taken.	by 10 January 2011		

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
The centre does not have a SOP guiding the procedure to be followed for withdrawal of consent to being the legal parent.	Standard licence conditions T33(b)	The PR should ensure that a SOP for the procedure to be followed for withdrawal of consent to being the legal parent is developed to ensure that no treatment is provided to a woman prior to all parties being informed of the change.	4 February 2011	Regarding the procedure to be followed for withdrawal of consent to being the legal parent a SOP has been created and circulated giving guidelines of the procedures to be followed. Copy of SOP sent with this response.	No further action required.
The centre does not have an SOP guiding the procedure for the withdrawal of consent for embryo storage	Standard licence condition T33 (b)	The PR should ensure the development of a SOP for the procedure to be followed for withdrawal of consent for embryo storage by one of the gamete providers, which	4 February 2011	Regarding the procedure to be followed for withdrawal of consent for embryo storage by one of the gamete	No further action required.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
by one of the gamete providers, which includes the provision of a 12 month “cooling off’ period and dispute resolution processes.		includes the provision of a 12 month “cooling off’ period and dispute resolution processes.		providers, which includes the provision of a 12 month “cooling off’ period and dispute resolution processes, a SOP has been created and circulated giving guidelines of the procedures to be followed. Copy of SOP sent with this response.	
The screening of donors does not fully conform to current professional body guideline.	Guidance Note 11.15	It is recommended that the PR reviews the current screening of donors to ensure that donors of gametes and embryos are screened and medically assessed in accordance with professional body guidelines.	4 February 2011	The sperm donor protocols have been amended to confirm all sperm donors will have a genital examination. The sperm and egg donor protocols will be amended by tomorrow to take into account the risk	No further action required.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				of spongiform disease transmission. Egg or sperm donors who have or have a first degree family member with prion-related disease, have undergone invasive neurological procedures or have received treatment using human tissue with the potential to transmit prion-related disease will not be accepted as donors. Completed 21.12.10	

Additional Information from the Person Responsible

Welfare of the Child Audit Summary:

The 'Welfare of the Child' assessment forms for all patients and partners having egg collection in December 2010 and those due to have egg collection in January 2011 were audited on 17th December 2010. A total of 80 forms were assessed. The completion of the forms by the patients was 100% complete. SEFC staff had failed to complete the 'To be Completed By Clinic' section on page three in 15 cases. Obviously these errors were completed at the time of audit. Although not required it was decided that the staff member completing the form should initial this page from now on.

To remedy the situation the Nursing team have been reminded that the form must be completed at the time of nurse consultation when planning treatment (if this has not been done at consultation with the doctor). The pre-treatment 'Nurses Checklist' requires a signature to confirm the form is complete. In addition a 'Doctor's Pre-Operative Checklist' has been introduced to ensure every form is looked at before egg collection to ensure it is complete. All staff have been reminded that the Welfare of the Child form must be renewed if the patient has not been seen for two years and that if a patient has a change of partner new forms must be completed for both parties.

A repeat audit will be carried out in three months to confirm improved compliance, 100% completion being the required standard.

HFEA Executive Licence Panel Meeting

21 January 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0208 (South East Fertility Clinic) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Ian Peacock, Analyst Programmer	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed by the HFEA since 2004 and has a history of good compliance. The Panel noted that the centre offers a comprehensive range of assisted reproductive therapies to both self funded and NHS contracted patients.

2. The Panel noted that the centre's inspection took place in November 2010, and that its current treatment and storage licence is due to expire in April 2014.

3. The Panel noted that the Inspectorate identified one major area of non-compliance and three other areas of non-compliance.

4. The Panel noted that the major area of non-compliance concerning the Welfare of the Child assessments being incomplete had now been addressed by the Person Responsible (PR).

5. The Panel noted that since the inspection the PR has now provided evidence to the Inspectorate, which they have reviewed and are now satisfied that all of the recommendations made on the inspection have now been addressed.

6. The Panel was satisfied with the response from the PR and the proactive response to address the recommendations within the report.

7. The Panel noted the Inspectorate's recommendation for the continuation of the centre's licence with no additional conditions.

Decision

8. The Panel endorsed the Inspectorate's recommendation to the continuation of the centre's licence, with no additional conditions.

Signed: Date: 2 FEL 2011
Mark Bennett (Chair)