HFEA Executive Licensing Panel Meeting

7 February 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0208 – (South East Fertility Clinic) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Mark Bennett – Director of Finance & Facilities (Chair)	Dee Knoyle
Nick Jones – Director of Compliance & Information	**Observing:** Sam Hartley – Head of Governance and Licensing
Joanne Anton - Policy Manager	

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

The Panel 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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 2007 and is on a five-year licence due to expire on 30 April 2014.

4. The Panel noted that in the 12 months to September 2013, the centre provided 578 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period July 2012 to June 2013 show the centre's success rates are in line with national averages.

6. The Panel noted that in 2012 the centre reported 40 cycles of partner insemination with five pregnancies. This is consistent with the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 22%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted that although the centre's success rates are consistent with the national average and multiple clinical pregnancy and live birth rates are not significantly different from the target, the Inspectorate encouraged the PR to continue to use the Quality Management System to monitor and continuously improve their success rates so as to improve the quality of the service offered to patients.

10. The Panel noted that at the time of the inspection in November 2013, the Inspectorate found no critical or major non-compliances and observed seven other areas of non-compliance. The Panel noted the PR's commitment to implement the outstanding recommendations within the prescribed timescales.

11. The Panel noted the Inspectorate recommended the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Decision

12. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

13. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

14. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

15. The Panel agreed to renew the centre's Treatment and Storage licence for four years, without additional conditions.

Signed: Date: 19 February 2014

Mark Bennett (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 19 and 20 November 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'

Inspection details:

The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland, Victoria Lamb, Susan Jolliffe, Chris Hall, Neil McComb, Zakia Ezzouya, Heidi Birch (observing).

Date of Executive Licensing Panel: 7 February 2014

Centre name	South East Fertility Clinic
Centre number	0208
Licence number	L/0208/7/a
Centre address	Amberley House, 9 Queens Road, Tunbridge Wells , Kent, TN4 9LL, UK
Person Responsible	Mr Michael Rimington
Licence Holder	Mr Mark Anthony Wilcox
Date licence issued	01 May 2009
Licence expiry date	30 April 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report ……3

This section provides a summary of findings, with key recommendations for improvement.

Section 2: Inspection findings ……7
This section provides the detail of findings from the inspection visit in the following areas:

- The protection of the patient, and children born following treatment
- The experience of patients and donors
- The protection of gametes (sperm and eggs) and embryos
- How the centre manages information

Section 3: Monitoring of the centre's performance ……17
This section provides information on the performance of the centre since the last inspection

Section 4: Areas of practice requiring action ……18
This section sets out the areas of practice that require the attention of the Person Responsible (PR) and the PR's response. Some of the requirements will have been met from the time of inspection to the publication of this report as shown in the summary, Section 1.

Section 1: Summary report

Brief description of the centre and its licensing history:
The South East Fertility Clinic has held a licence with the HFEA since 2007 and provides a full range of fertility services.

The centre provided 578 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to September 2013. In relation to activity levels this is a medium sized centre.

Activities of the centre:

Type of treatment	Number of treatment cycles for the period *01 October 2012 – 30 September 2013
In Vitro Fertilisation (IVF)	180
Intracytoplasmic sperm injection (ICSI)	244
Frozen embryo transfer (FET)	105
Donor insemination (DI)	49
Egg donation (non egg share)	8

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

Outcomes [1]

For IVF and ICSI, HFEA held register data for the period July 2012 to June 2013 show the centre's success rates are in line with national averages.

In 2012 the centre reported 40 cycles of partner insemination with 5 pregnancies. This equates to a 12% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 22% this represented performance that was not statistically different from the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20% this represented performance that was not likely to be statistically different than 15% multiple live birth rate target for this period.

[1]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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Executive Licensing Panel is asked to note that at the time of the inspection there were seven "other" areas of non-compliance which resulted in the following recommendations:

'Other' areas of non-compliance or poor practice that require improvement:

- the PR should ensure that Quality Indicators (QI's) are established for all licensed activities;
- the PR should ensure that following an audit of licensed activities, the corrective actions are implemented and documented;
- the PR should ensure that the content of third party agreements is compliant with Standard Licence Condition (SLC)T114;
- the PR should ensure that where possible only CE marked medical devices are used;
- the PR should ensure that staff are competent to perform their designated tasks;
- the PR should ensure that additional testing is performed depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi);
- the PR should ensure that the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms.

The PR has given a commitment to implement all of the recommendations.

Recommendation to the Executive Licensing Panel:

The centre has no critical or major of areas of non-compliance.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates are not significantly different from the target. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and continuously improve their success rates so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

Nothing noted on inspection.

Patient and donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and / or donors

The centre's procedures for screening patients and donors are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors

Payments to donors are fully in line with the requirements of the HFEA. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception

People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that

centre's use donated gametes or embryos from identifiable donors. The centre is fully in line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Screening of patients and / or donors
The centre does not carry out required additional testing depending on the patient's and donors travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi). SLC T52(h) (SLCT50(d))

See recommendation 6

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The progress in reducing the clinical multiple pregnancy rates suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

Process Validation(Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (Guidance note 23)
The centre has a quality management system in place that is broadly compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre's procedures are broadly compliant with HFEA third party agreements requirements.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff, however not all are CE marked as discussed below.

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licenced activities are conducted in a suitable environment that is fit for purpose.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Quality management system (Guidance note 23)
Quality indicators have not been established for all activities (SLCT35).
See recommendation 1.

Staff could eloquently describe aspects of the quality management system including some quality indicators and audit work. However, there was no system to document and feedback the findings of the audit reports to ensure corrective action was identified and implemented. (SLCT36).
See recommendation 2

Third party agreements (Guidance note 24)
A sample of third-party agreements reviewed in the course of the inspection did not meet the requirements of standard licence condition T114 (e)&(f)It was noted that all agreements used a specific template which did not include the following:

- any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety and /or where relevant a description of how any test/diagnostic results are relayed to the commissioning centre including

sign off and confirmation that the result applies to the correct sample.
Examples of the third party agreement with the courier responsible for the collection and transporting of samples and the laboratory responsible for performing screening tests on behalf of the centre (SLCT114).
See recommendation 3

Equipment and materials (Guidance note 26)
The pipettes used at the centre are not CE marked (SLCT30).
See recommendation 4

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable, and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme T/1101/7.

Staff (Guidance Note 2)
The centre is broadly compliant with HFEA requirements.

What the centre could do better.

Staff (Guidance Note 2)
Whilst the PR provided verbal confirmation of his confidence in the competencies of the centre team, not all individuals working in the centre could provide documented assessment of competencies for all of the designated tasks that they perform including recruitment and assessment of donors and storage of gametes and embryos (SLCT15 (a)).
See recommendation 5

Welfare of the child (Guidance note 8) **and safeguarding**

What the centre does well.

The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

Safeguarding

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

What the centre could do better.

Nothing noted on inspection

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspector(s) spoke to two patients who provided positive feedback on their experiences. A further 21 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 17 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better.

Nothing noted on inspection.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; Direction 0001)

The centre does not provide treatments involving gamete sharing.

Surrogacy (Guidance note 14)

The centre does not provide treatments involving surrogacy.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)

The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)

The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors.

What the centre could do better.
Nothing noted on inspection

Information

What the centre does well.

The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of costed treatment plan (Guidance note 4)
The centre provides an individual costed treatment plan where relevant to all of its patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.
Nothing noted on inspection.

Consent

What the centre does well.

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

What the centre could do better
The centre's procedures for taking and recording consent to disclosure do not fully ensure that the HFEA holds an accurate record of the patients consent.
An audit performed on the day of inspection of the reporting of consent to disclosure decisions for 29 patients suggested there were four discrepancies between what was reported to HFEA and the consents documented in the patient records. Subsequent to the review of the inspection report by the PR it was clarified that there were only two discrepancies between completed patient/partner disclosure consents in the patient files and the data submitted for inclusion on the register.
See recommendation 7.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises.
- Only permitted embryos are used in the provision of treatment services.
- Embryos are not selected for use in treatment for social reasons.
- Embryos are not created by embryo splitting.
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman.
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better.
Nothing noted on inspection.

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

What the centre could do better
Nothing noted on inspection

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are broadly compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to

permit the gametes and embryos be stored or used in a way that does not compromise their quality and safety.

What the centre could do better

The documented agreement in place with the courier responsible for the transporting of gametes and embryos does not specify that required conditions are maintained during distribution (CoP mandatory requirements 15C).

See recommendation 3

Use of embryos for training staff (Guidance note 22)

What the centre does well.

The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The centre uses embryos to train staff in the following activities:

- Cryopreservation and thawing techniques
- Vitrification
- Assisted hatching
    - Mechanical
    - Chemical
    - Laser
- Embryo handling and manipulation
- Assessment of embryos

All of these activities have been authorised by the Authority.

What the centre could do better.

Nothing noted on inspection

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are fully compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

A small number of minor errors were found during the review of source data against data submitted to the register. The centre team is in the process of correcting these errors and therefore the inspection team consider that a recommendation is not required. SLC T9(e) / T41 Direction 0005

Section 3: Monitoring of the centre's performance

Following the interim inspection in November 2012, recommendations for improvement were made in relation to one area of critical non-compliance, one area of major non-compliance and one 'other' area of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented.

The following recommendations have now been implemented but were not completed within the required timescales:

- The PR should audit a sample of patient and partner consent to disclosure to researchers documented in patient records against consent decisions recorded in the HFEA register to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent.

On-going monitoring of success rates

In the last year, the centre was asked to review procedures for the provision of IVF treatment in woman aged under 38.

The PR did not respond formally to the HFEA regarding this alert however the brief negative trend in results has been reversed and the centre did not receive any further alerts regarding success rates.

Areas of practice requiring action

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

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, embryo or to a child who may be born as a result of treatment services
- 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 and reference	Action required and timescale for action	PR Response	Executive Review
None			

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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre team has not established quality indicators for all non-critical activities. SLCT35	The PR should ensure that quality indicators are established for all activities. The PR should provide the inspector with a list of quality indicators by 20 February 2014.	Agreed. The Quality Management Team has met to draw uo the QI's as recommended. These, in turn, will be audited as part of our ongoing audit programme.	The inspector looks forward to receiving the list of Quality Indicators by 20 February 2014. Further action needed.
2. The centre team does not have a robust system for recording the corrective actions following audits of the centre's activities SLC T36.	The PR should, where possible, review the findings of the audits for which there was no documentation of corrective actions. The HFEA should be provided with a summary report documenting any required corrective actions and the timescale for their implementation by 20 February 2014. Where it is not possible to establish the corrective actions	Agreed. The audit policy is being reviewed. The plan is to report any issues which arise from audits as non-conformances. These are reviewed at the monthly Management Meetings in order to decide what corrective action is required. The non-conformance can be signed off once that corrective action has been taken and a further audit planned.	The inspector looks forward to receiving the summary report by 20 February 2014. Further action needed.

	identified as required by audits then consideration should be given to repeating these audits: the HFEA should be advised of the anticipated timescale for repeat of any audits where the corrective actions cannot be established by 20 February 2014.		
3. The content of a sample of third-party agreements reviewed in the course of the inspection did not meet the requirements of standard licence condition SLC T114. The agreements did not include the following: a summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities / any specific criteria that the service provided by the third party must meet,	The PR should ensure that all TPAs are reviewed to ensure compliance with SLC T114. A summary report of the findings of the review including a list of all third party agreements included in the review should be provided to the HFEA by 20 February 2014. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions. By 20 February 2014.	The third party agreements will be reviewed as requested. The Quality Manager will be seeking further guidance on the precise requirements from the HFEA.	The inspector is happy to discuss the requirements with the Quality Manager and looks forward to receiving the review by 20 February 2014. Further action needed.

particularly in relation to quality and safety or a description of how any test/diagnostic results are relayed to the commissioning centre including sign off and confirmation that the result applies to the correct sample. SLC T114(d,e)			
4. The pipettes used by the centre are not CE marked. SLC T30	Wherever possible only CE marked medical devices should be used. The PR should respond with an action plan to address this by 20 February 2014. The actions agreed should be implemented by 20 May 2014 and the centre's inspector should be informed that this has happened.	Agreed. It is anticipated that we will use all CE marked equipment in the proposed timescale.	The inspector is happy with the response and requests confirmation that the agreed actions have been completed by 20 May 2014. Further action needed.
5. The centre team could not provide documented evidence of competency assessments for all of the designated tasks that they perform. SLC T15 (a).	The PR should ensure that a competency framework is in place and that the competencies of all staff at the centre are assessed and documented. By 20 April 2014	Agreed. The administrative, nursing and clinical competency framework is in place. We know the laboratory competencies are not complete and we will roll out a comprehensive competency programme within the proposed timescale.	The inspector looks forward to receiving confirmation of the establishment of the competency programme by 20 April 2014. Further action needed.

6. The centre does not carry out required additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi). SLC T50(d) T 52 (h)	The PR should take immediate action to ensure that procedures are established to identify when additional testing may be indicated and to develop procedures for carrying out additional testing. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by a Licensing Committee. Within three months of the implementation of procedures, the centre should conduct an audit of screening and a summary report of the findings of the audit should be provided to the HFEA. Immediately	Disagree. We DO carry out additional testing if required. The patient history sheet in our electronic records already specifies whether the patient has come from or travelled abroad. To reassure the Licence Panel, we have added a line to the hisory sheet which requires the clinician to state 'yes' or 'no with regard to whether further testing is required.	The inspector acknowledges the PR's comments and has reviewed SOP's submitted in their support. Whilst the inspector is satisfied that the centre do take into account when additional testing is required it was considered that the SOP's do not contain sufficient detail to satisfy licence condition T50(d) and T52(h). The inspector has discussed this with senior embryologist at the centre and it has been agreed that the SOP's will be amended and the audit performed. Further action required.
7. An audit performed on the day of inspection of the reporting of consent to disclosure decisions for 29 patients suggested there were four discrepancies	The PR should review systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on	All discrepencies have now ben corrected. The record keeping wiil be audited again as recommended. Some of the audit observastions were incorrect. I	The inspector looks forward to receiving the audit summary by 20 May 2014. Further action needed.

	between what was reported to HFEA and the consents recorded in the patient records. Subsequent to the review of the inspection, report by the PR it was clarified that there were only two discrepancies between completed patient/partner disclosure consents in patient files and the related consent data submitted for inclusion on the register.	completed disclosure consent forms. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. By 20 May 2014	would refer you to the e-mail correspondence with Chris Hall.	

Response from the Person Responsible to this inspection report