HFEA Executive Licensing Panel Meeting

24 April 2014

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

Minutes – Item 1

Centre 0291 – (Fertility Unit Barking, Havering and Redbridge Hospitals Trust) Renewal Treatment (insemination using partner sperm) Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair) David Moysen – Head of IT Joanne Anton – Policy Manager	Dee Knoyle

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 centre has held a Treatment (insemination using partner sperm) licence with the HFEA since 2007 and has a four-year licence due to expire on 31 July 2014. The centre provides basic fertility services and in relation to activity levels this is a small centre.

3. The Panel noted that the former Person Responsible (PR) retired from his position in March 2014 and a new PR has recently been approved by the Executive Licensing Panel.

4. The Panel noted that in 2012, the centre performed 86 cycles of IUI with eight pregnancies. This equates to a nine per cent clinical pregnancy rate. The centre did not submit its data within the timeframe specified and therefore the results were not included in the statistical analysis of the sector's results.

5. The Panel noted that, the centre has submitted its treatment outcome data for 2013, performing 109 cycles of IUI with five pregnancies. This equates to a five per cent clinical pregnancy rate. The Panel noted that HFEA analysis of the sector's results for 2013 has not yet been performed; therefore a comparison of the centre's 2013 results against the national average cannot be made yet.

6. The Panel noted that the centre's clinical pregnancy rate has triggered a requirement for review by the centre's quality management system (QMS). The Panel noted that a detailed investigation is currently underway.

7. The Panel noted that at the time of the inspection on 23 January 2014, the Inspectorate observed five major and nine other areas of non-compliance. In particular, it noted that two of the non-compliances identified at the last inspection, relating to consent and to staffing, have not been implemented. The Panel noted that since the inspection the centre has provided confirmation that some of the recommendations have been fully implemented, however the majority are outstanding. The Panel urged the new PR to fully implement the recommendations within the prescribed timescales.

8. The Panel noted that the centre is undergoing a period of change, with a new PR and uncertainty over the future of the service and fully supports the Inspectorate's recommendation to support the new PR with close monitoring of the centre's performance and to perform a focussed interim inspection within a year of the licence renewal date. The Panel noted the new PR's commitment to fully implement the outstanding recommendations.

9. The Panel noted that the Inspectorate recommended the renewal of the centre's Treatment (insemination using partner sperm) licence for a period of three years without additional conditions, subject to compliance with their recommendations being fully implemented within the prescribed timescales. The Panel supports the Inspectorate's recommendation that failure to

implement the recommendations relating to these major areas of non-compliance within the prescribed timescales will result in the submission of a further report to the Executive Licensing Panel with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

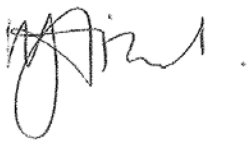
Decision

10. 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.

11. 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).

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

13. The Panel agreed to renew the centre's Treatment (insemination using partner sperm) licence for three years, without additional conditions, and a focused interim inspection performed within one year of the renewal date of the licence.



Signed: Date: 2 May 2014

Juliet Tizzard (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. 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: 23 January 2014

Purpose of inspection: Renewal of a licence to carry out 'Treatment (Insemination using Partner Sperm)'

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: Sara Parlett (Lead) and Gill Walsh

Date of Executive Licensing Panel: 24 April 2014

Centre name	Fertility Unit Barking, Havering and Redbridge Hospitals Trust
Centre number	0291
Licence number	L/0291/3/c
Centre address	Queens Hospital, Rom Valley Way, Romford, Essex, RM7 0AG
Person Responsible	Mr Satha Sathanandan
Licence Holder	Mr Stephen Burgess
Date licence issued	1 August 2010
Licence expiry date	31 July 2014
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Fertility Unit Barking, Havering and Redbridge Hospitals Trust has held a 'Treatment (Insemination using Partner Sperm)' licence with the HFEA since 2007 and provides basic fertility services. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The Person Responsible (PR) plans to retire from his position in March 2014 and there has been some uncertainty as to the Trust's plans for the fertility service after this date. The PR explained that new National Institute for Health and Care Excellence (NICE) guidelines have significantly reduced the recommended clinical indications for IUI treatment and as a consequence it is likely that few new IUI cycles will be performed at the centre. Only patients already undergoing the three IUI cycles previously commissioned by Clinical Commissioning Groups (CCGs) for certain patient groups prior to referral for IVF treatment are being treated currently and these are likely to be completed by February 2014. However, in December 2013 it was confirmed that the Trust planned to support the renewal of the centre's current licence whilst also considering plans to establish a full IVF centre at the hospital.

An application to vary the centre's licence to appoint a new PR has been received and has been scheduled for consideration by an ELP in March 2014.

Centre's activity levels:

Type of treatment	Number of treatment cycles 01 January 2013 - 31 December 2013
Intrauterine insemination (IUI)	109

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	N/A
Storage of embryos	N/A
Embryo testing	N/A

Pregnancy outcomes

In 2012, the centre performed 86 cycles of IUI with eight pregnancies. This equates to a nine per cent clinical pregnancy rate. The centre did not submit its data within the timeframe specified and therefore the results were not included in the statistical analysis of the sector's results.

The centre has submitted its treatment outcome data for 2013, performing 109 cycles of IUI with five pregnancies. This equates to a five per cent clinical pregnancy rate. HFEA analysis of the sector's results for 2013 has not yet been performed; therefore a comparison of the centre's 2013 results against the national average cannot be made yet. However, this clinical pregnancy rate has triggered a requirement for review by the centre's own quality management system (QMS). The laboratory manager described the detailed investigation currently underway.

Multiple births[1]

The single biggest risk of fertility treatment is a multiple pregnancy. During 2013 the centre reported one multiple pregnancy.

[1]The HFEA does not perform any statistical analysis of multiple birth rates following IUI treatment to determine whether the multiple birth rates are statistically different from national targets because the number of treatments is usually small.

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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major and nine 'other' areas of non-compliance.

Since the inspection visit, the centre has provided confirmation that the following recommendations have been fully implemented:

'Other' areas of non compliance:

- The PR should ensure that all relevant data about anything coming into contact with gametes is traceable.
- The PR should ensure that annual returns for IUI treatment are submitted to the HFEA within the required timeframe.

The PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that audits are performed for all licensed activities and activities carried out in the course of providing treatment services that do not require a licence.
- The PR should ensure that the centre is operating with a full staff complement.
- The PR should ensure that all staff participate in relevant professional development.
- The PR should seek patient feedback for all aspects of the service provided, to assess the patient experience.
- The PR should review the processes for seeking consent relevant to the licensed treatment provided by the centre.

'Other' areas of non compliance:

- The PR should ensure that standard operating procedures (SOPs) are in place to direct all relevant activities.
- The PR should ensure that for all established quality indicators (QIs), the frequency of audit/review is documented.

- The PR should ensure that only CE marked consumables are used, where suitable alternatives are available.
- The PR should ensure the centre's adverse incident SOP includes details of HFEA reporting mechanisms and requirements. Training in HFEA incident reporting should be given to all centre staff.
- The PR should review the centre's patient information leaflets to ensure that the information provided is clear and consistent.
- The PR should ensure that records are kept for at least 30 years.
- The PR should ensure that fees are paid to the Authority within the timescale specified.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have five major areas of concern. Two of these were issues identified at the last inspection, for which recommendations have not been implemented.

Significant improvement is required in order for the centre to reflect suitable practices. The inspection team considers that the failure to provide appropriate patient information and obtain relevant consent represents a serious risk. Further, it is not considered that the centre's QMS is used to best effect to monitor and improve the service provided. For example, a lack of audit of all aspects of clinical practice has contributed to the persistent poor consenting practices.

The proposed new PR did confirm soon after the inspection visit that several recommendations were already in the process of being implemented and a commitment to action all inspection recommendations was made. However, due to the significant improvement required and the centre undergoing a period of change, with a new PR and uncertainty over the future of the service, the inspection team considers that close monitoring of the centre's performance would be appropriate.

The inspection team recommends the renewal of the centre's 'Treatment (Insemination with Partner Sperm)' licence for a period of three years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales. Failure to implement the recommendations relating to these major areas of non-compliance within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends that the centre works closely with the HFEA and that a focussed interim inspection is performed within a year of the licence renewal date.

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) 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 identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

The centre does not provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable to this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway

Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

The premises of the laboratories conducting tests that impact on the quality and safety of gametes are suitable.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients or their gametes are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
This area of practice is not yet being covered by HFEA inspections of IUI only centres. This area remains covered by the Trust's overarching registration with the Care Quality Commission (CQC).

Medicines management
This area of practice is not yet being covered by HFEA inspections of IUI only centres. This area remains covered by the Trust's overarching registration with the CQC.

Pre-operative assessment and the surgical pathway
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre does not distribute gametes or embryos therefore this area of practice is not applicable to this inspection.

Receipt of gametes and embryos (Guidance note 15)
The centre does not receive distributed gametes or embryos therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; Directions 0006)
The centre does not distribute or receive distributed gametes or embryos therefore this area of practice is not applicable to this inspection.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability to:

- identify and locate gametes during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes;
- identify any person who has carried out any activity in relation to particular gametes; and
- identify and locate all relevant data relating to products and materials coming into contact with particular gametes which can affect their quality or safety.

Quality management system (Guidance note 23)
The centre has a QMS in place that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have transport and satellite links therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements, with one exception detailed below. 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.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are broadly compliant with HFEA requirements. The centre has not had any HFEA reportable adverse incidents (including serious adverse events and reactions), therefore how the centre reports and investigates its adverse incidents in practice could not be reviewed. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Traceability (Guidance note 19)
The specimen containers used to collect sperm samples are provided by the Trust's central stores department without accompanying details of the batch number or expiry date. Relevant data about this product is therefore not recorded (Standard Licence Condition (SLC) T99). The inspection team is also concerned that there is a risk that containers could be used after the expiry date. The laboratory manager identified this as an issue during a traceability audit and is seeking a resolution with the Trust. See recommendation 6.

Quality management system (Guidance note 23)
The centre does not have SOPs describing the procedures for:

- providing information to patients;
- taking effective consent;
- Welfare of the Child (WoC) assessment (SLC T33b). See recommendation 7.

The centre has established QIs for all activities, but the frequency of audit is not documented in all cases (SLC T35). See recommendation 8.

In the last two years, the centre has not audited how far the following procedures comply with the approved protocols, the regulatory requirements and QIs:

- provision of information;
- taking effective consent;
- WoC assessment (SLC T36). See recommendation 1.

The above non-compliances and other issues referenced elsewhere in the report raise concerns that the QMS is not being used effectively to continually improve the quality and effectiveness of the service provided (SLC T32).

Equipment and materials (Guidance note 26)
Serological pipettes used by the centre are not CE marked (SLC T30). However, the laboratory manager is aware of this and confirmed that a CE marked alternative had been sourced and would be used once new stock was required (expected mid-2014). An audit performed by the centre confirmed that all other relevant consumables used are CE marked. See recommendation 9.

Adverse incidents (Guidance note 27)
The centre has a documented procedure for the management and reporting of incidents to the Trust. However, there is no reference to HFEA reporting mechanisms and requirements (SLC T118). Less senior staff were unclear of HFEA reporting requirements although the inspection team was satisfied that they would report any issues to a senior

member of staff (SLC T15d). See recommendation 10.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has broadly ensured compliance with HFEA requirements.

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 (PREP number T/1136/7).

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements. The centre has suitably qualified and competent staff, to carry out the licensed activities and associated services.

The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
The inspection team was concerned that staffing levels may be inadequate for the activities being undertaken (SLC T12). This is based on the following:

- a recommendation to conduct one audit was made by the HFEA in March 2012. This has not yet been performed and the PR explained that this was due to staff shortage;
- other areas of concern noted on inspection have been attributed to inadequate resources (for example, a lack of patient satisfaction surveys);
- staff feedback.

However, it is not clear if staff complement will continue to be an issue with the anticipated reduction in activity levels. See recommendation 2.

Not all staff at the centre participate in relevant professional development. This was an issue at the previous inspection and the PR gave a commitment then that the lead nurse would organise a structured fertility continued professional development (CPD) programme. The laboratory manager continues to fund his own CPD and a senior nurse has not had an opportunity for fertility related CPD since before the last inspection. This raises concerns about how all staff can keep up with changes and improvements to patient care (SLC T15). See recommendation 3.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the WoC are broadly compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

Safeguarding
This area of practice is not yet being covered by HFEA inspections of IUI only centres. This remains covered by the Trust's overarching registration with the CQC.

What the centre could do better

Welfare of the child (Guidance note 8)
The centre does not have an SOP describing the procedure for WoC assessment (SLC T33b) (see 'suitable premises and suitable practices' section of this report and recommendation 7).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

The centre does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

Refer to 'what the centre could do better' section, below.

What the centre could do better

There were no patients available during the inspection visit to provide feedback on their experiences. No patient feedback has been provided directly to the HFEA since January 2011 although centre staff confirmed that patients have been provided with the HFEA questionnaires to complete.

The centre does not perform patient satisfaction surveys, although the laboratory manager has recently commenced gathering patient feedback regarding andrology aspects of the service but the results have not yet been reviewed.

No evidence was therefore available to allow the inspection team to assess patient satisfaction with the service provided by the centre. It is also unclear how the centre staff act to effectively improve the service offered if they have not actively sought feedback from patients (CoP Guidance 23.17 and SLC T32). See recommendation 4.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The HF&E Act 1990 (as amended) does not require the offer of counselling support to IUI patients therefore this area of practice is not applicable to this inspection.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre does not provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to be responsive to patient complaints. This is important to ensure that the centre uses any complaints as an opportunity to learn and improve their services.

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 wellbeing of prospective and current patients.

What the centre could do better

Complaints (Guidance note 28)
The complaints management process was discussed with the Directorate's Matron. Whilst this Directorate wide system is in line with the Trust's policy it was agreed that it was difficult for centre staff to be alert to and respond early and directly to fertility patient complaints or concerns. It was agreed that as part of a review of the service this would be addressed. Immediately post inspection, centre staff submitted details of a new complaints log book that would be held at the centre. The inspection team considers that no formal recommendation is required.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients are partially compliant with HFEA requirements. These requirements ensure that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information (Guidance note 4; CH(11)02)
The inspection team considers the patient information leaflets are unclear in some areas, for example several words are abbreviated and it is not obvious that patients will understand these abbreviations. There is also inconsistency between information regarding the day on which a pregnancy test should be performed after the IUI procedure (SLC T58). See recommendation 11.

The centre does not have an SOP describing the procedure for providing information to patients (SLC T33b) (see 'suitable premises and suitable practices' section of this report and recommendation 7).

The inspection team was concerned that the consent issues documented below indicate that patients may not have received accurate information about the implications of giving consent (SLC T58). See recommendation 5.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5)
The centre's procedures for obtaining consent are partially compliant with HFEA requirements. These requirements ensure that patients have provided all required consents before carrying out any licensed activity.

What the centre could do better

Consent (Guidance note 5)
A review of five patient records conducted on inspection demonstrated that where couples are unmarried, the female partner is required to complete an HFEA WP consent form. This consent form is relevant to legal parenthood only when donor sperm is used.

Disclosure of information, held on the HFEA Register, for use in research (Direction 0005)
The review of patient records also demonstrated that patients were being asked to consent to disclosure of their treatment information to researchers. The HFEA does not hold any information about patients' IUI treatments and so these consent forms are not relevant to this patient group.

The inspection team was concerned that both of the above issues indicate that staff do not fully understand the nature of the consent they are seeking and that as a result, patients may not have received accurate information about the implications of giving consent (SLC T58).

See recommendation 5.

The centre does not have an SOP describing the procedure for taking consent (SLC T33b). (see 'suitable premises and suitable practices' section of this report and recommendation 7).

3. The protection of gametes and embryos

Respect for the special status of the embryo
What the centre does well The centre does not create embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

Screening of patients **Storage of gametes and embryos**
What the centre does well **Screening of patients (Guidance note 17)** The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment and processing of gametes. **Storage of gametes and embryos (Guidance note 17)** The centre does not store gametes or embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well The centre does not create or store embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

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; Direction 0005)
Centres providing basic partner treatment services are required to submit an annual return to the HFEA providing details of the number of treatments performed and the outcomes of those treatments. This enables the HFEA to satisfy its statutory reporting responsibilities and to provide information to patients via the HFEA website about centres' success rates.

What the centre could do better

Record keeping and document control (Guidance note 31)
The centre does not have procedures in place to ensure that records are kept for at least 30 years. An audit report reviewed on inspection stated that patient notes are retained for 25 years (SLC T48). See recommendation 12.

Obligations and reporting requirements (Guidance note 32; Direction 0005)
The centre did not provide an annual return for treatments undertaken in 2012 within the required timeframe (General Direction 0005). Post inspection, annual returns for 2012 and 2013 were submitted. See recommendation 13.

Payment of the invoice for HFEA annual fees provided to the centre in July 2013 remained outstanding at the time of inspection. This invoice has subsequently been paid. (SLC T9(d)). See recommendation 14.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to two major and three 'other' areas of non-compliance.

The PR provided information and evidence that the two major and one of the 'other' areas of non-compliance were fully implemented.

The following recommendations have not been implemented:

- The PR should ensure that staff are supported in their on-going CPD to maintain registration with their respective professional bodies and demonstrate adequate knowledge and understanding of the relevant clinical/scientific processes to perform their designated tasks. This was due for completion in September 2012. Despite several requests to the PR for an update, this remains outstanding.

- The PR should ensure that the information giving process to patients and their partners is audited against the approved protocols, regulatory requirements and the centre's own QIs. This was due for completion in September 2012 and despite several requests for action this remains outstanding. The PR stated that due to acute shortage of staff this could not be completed.

Refer to 'suitable premises and suitable practices' and 'staff engaged in licensed activity' sections of this report for further details.

On-going monitoring of centre success rates

Success rates for IUI treatment are not monitored through the HFEA's risk tool.

Centre staff have however identified a fall in their clinical pregnancy rates in 2013. On inspection, the laboratory manager described the detailed investigation that is currently being performed. HFEA analysis of the sector's results for 2013 has not yet been performed; therefore a comparison of the centre's 2013 results against the national average cannot be made yet. However, if this analysis does demonstrate that the centre's results are below national average, the outcome of this review and the effect of any corrective actions identified and implemented will be followed up via on-going monitoring by the centre's inspector.

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
Nothing identified.			

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
1. In the last two years, the centre has not audited how far the following procedures comply with the approved protocols, the regulatory requirements and QIs: • provision of information; • taking effective consent; • WoC assessment. SLC T36. **This was an issue at the previous inspection.**	The PR should provide the HFEA with an audit schedule documenting all activities to be audited and an anticipated timescale for completion of the audit programme by the time the PR responds to this report. Monthly updates should then be provided to the centre's inspector. It is expected that these audits will be completed by 23 July 2014.	Number of audits were initiated by our clinical fellow after our last intrim inspection two years ago. However, due to events not congenial to the staff interactions and ultimatley patient care,the trust terminated clinical fellows' position. As a result the audits started were not completed. New audits are currently being registered and monthly updates will be provided to the centre's imspector with a summary of the completed audits by the 23rd of July 2014.	The Executive notes the PR's commitment to undertake this recommendation but reminds him that an audit schedule should have been submitted. It is requested that this is submitted to the lead inspector by 15 April 2014. The completion of these audits will be followed up by the Executive through the on-going monitoring system.
2. The centre is not operating with a full staff complement.	The PR should assess how many cycles of treatment can be safely accommodated	As the unit practices evidence based medicine, it is anticipated that there will eb a	The lead inspector acknowledges the PR's response but reminds him that

However, it is not clear that staff complement will continue to be an issue with the anticipated reduction in activity levels. SLC T12.	taking into account staffing levels, the skills mix and competence of staff, equipment and premises. It should also take into account the resources required to implement the recommendations made in this report. A copy of the assessment should be submitted to the HFEA by 23 April 2014. The PR should ensure that workload is maintained within the safe limits determined in this assessment.	reduction in the number of IUI cycles being offered to our patients. In view of this change in the unit's policy, the full compliment of staff will not continue to be a problem. However, the staffing lelevs will be monitored regularly.	a formal work force assessment should be performed and a copy of this assessment should be submitted by 23 April 2014. This will be subject to on-going monitoring.
3. Not all staff at the centre participate in relevant professional development. This raises concerns with how all staff can keep up with changes and improvements to patient care without this commitment to CPD. SLC T15. **This was an issue at the previous inspection.**	The PR should ensure that all staff have an opportunity to participate in CPD. The PR should undertake a review of the professional development undertaken by staff members and provide a summary report documenting the findings of the review to the HFEA. The summary report should document any corrective actions required and the timescale for the implementation of the corrective actions. A copy of the summary report should be	The management is aware of the need to implement a CPD programme for all their staff. To this end, the Women's Health Care Matron has been asked to draw up an action plan ensuring an ongoing CPD for all the nurses and Health Care Scientist. A schedule of proposed activities will be forwarded to the unit's Inspector by 31st of March 2014.	The lead inspector acknowledges the PR's response but reminds him that a formal CPD review should be performed and a copy of this assessment should be submitted by 23 April 2014. This will be subject to on-going monitoring.

	provided to the HFEA by 23 April 2014. The PR should provide quarterly updates to the HFEA on progress in implementing corrective actions.		
4. The centre does not conduct patient satisfaction surveys for all areas of activity. It is unclear how the centre staff act to effectively improve the service offered if they have not actively sought feedback from patients. CoP Guidance 23.17 and SLC T32.	The PR should seek patient feedback for all aspects of the service, to assess the patient experience. The PR should audit the results and provide the inspector with a copy of the findings including any corrective actions identified by 23 July 2014.	An overall patient satisfaction survey is currently being registered and is expected to start on the 1st of April. The results of this survey will be audited a copy of the findings including any corrective actions implemented will be submitted to the HFEA by 23rd of July 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
5. **Consent** A review of five patient records conducted on inspection demonstrated that where couples are unmarried, the female partner is required to complete an HFEA WP consent form. This consent form is relevant to legal parenthood only when donor sperm is used.	The PR should review the processes for seeking consent relevant to the licensed treatment provided by the centre. A summary of the review and corrective action identified and implemented should be submitted by the time the PR responds to the report.	As of 24th of January 2014, the female partner of anunmarried couple no longer completes the HFEA WP consent form. Furthermore, consent to disclosure of their treatment information to researchers has also been stopped as HFEA does not hold any information about	The lead inspector acknowledges the PR's response and considers that the actions taken will have reduced the risk of failing to provide appropriate information and obtain relevant consent. The PR should provide the

The review of patient records also demonstrated that patients were being asked to consent to disclosure of their treatment information to researchers. The HFEA does not hold any information about patients' IUI treatments and so these consent forms are not relevant to this patient group. The inspection team was concerned that both of the above issues indicate that staff do not fully understand the nature of the consent they are seeking and that as a result, patients may not have received accurate information about the implications of giving consent. SLC T58.	The PR should ensure staff are provided with suitable training to ensure that appropriate information is provided prior to consent and that the consent sought is effective and relevant to the licensed treatment to be provided. Evidence of this should be submitted by the time the PR responds to the report.	patients' IUI treatment. A trainning programme for all staff to ensure that appropriate information is provided prior to consent and that the consent sought is effective and relevant to the licensed tretament to be provided has been implemented.	centre's inspector with an update on the progress with the training programme by 23 July 2014.

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
6. The specimen containers used to collect sperm samples are provided by the Trust's central stores department without accompanying details of the batch number or expiry date. Relevant data about this product is therefore not recorded. The inspection team is also concerned that there is a risk that containers could be used after the expiry date. The laboratory manager is aware of this issue and is seeking a resolution with the Trust. SLC T99.	The PR should ensure that all relevant data about anything coming into contact with gametes is traceable. The PR should inform the centre's inspector when a solution has been reached with the Trust and by 23 July 2014 at the latest.	A new supplier has ben identified who is able to provide all the nercessary traceability information. We changed our supplier at the end of January 2014 and a Third Party agreement has been entered into with the supplier.	The lead inspector acknowledges the PR's response. No further action is required.
7. **SOPs** The centre does not have SOPs describing the procedures for: • providing information to	The PR should ensure that SOPs are in place to direct all relevant activities. The audits required by	SOPS are being prepared to reflect the procedures for a) providing information to patients, b) taking effective consent and c) Welfare of	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

patients; • taking effective consent; • WoC assessment. SLC T33b.	recommendation 1 cannot be comprehensively performed without these SOPs and therefore the timescale for implementation of this recommendation will reflect the schedule to be provided for recommendation 1.	Child assessment. Once the SOPs an dteh work instructions related to them are completed it is anticipated that an audit will be carried out against these SOPs and an intrim report of the audit and corrective actions taken will be forwarded to the HFEA by the end of July 2014.	
8. The centre has established QIs for all activities, but the frequency of audit/review is not recorded in all cases. SLC T35.	The PR should ensure that the frequency of audit/review is documented for all QIs. The centre's revised QI list should be provided by the time the PR responds to this report.	A list is attached of all the QIs for all the activities with the frequency of audit/review clearly indicated. Although this information was not on the QIs,the unit has been carrying out audit's on an annual basis.	No attachments were received. The Executive requests that the revised QI list is submitted to the lead inspector by 15 April 2014.
9. Serological pipettes used by the centre are not CE marked. However, the laboratory manager was aware of this and confirmed that a CE marked alternative had been sourced and would be used once new stock was required (expected mid-2014). SLC T30.	The PR should ensure that wherever possible CE marked medical devices are used. The PR should inform the centre's inspector when the use of a suitable CE marked alternative is introduced and by August 2014 at the latest.	CE marked new stock i sbeing introdcued on the 1st of August 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
10. The centre has a documented procedure for	The PR should ensure the centre's adverse incident SOP	An adverse incident SOP is currently being reviewed to	The lead inspector acknowledges the PR's

the management and reporting of incidents to the Trust. However, there is no reference to HFEA reporting mechanisms and requirements. Less senior staff were unclear of HFEA reporting requirements although the inspection team was satisfied that they would report any issues to a senior member of staff. SLC T118 and T15d.	includes details of HFEA reporting mechanisms and requirements. Training in HFEA incident reporting requirements should be given to all centre staff. A copy of the revised SOP and evidence of completion of training should be submitted to the centre's inspector by 23 April 2014.	take into consideration the hFEA reporting mechanisms and requirements. A training in HFEA incident reporting requiremnet has been organised for all staff at the end of March 2014. A copy of the revised SOP and evidence of completon of training will be submitted to the centre's inspector by 23rd of April 2014.	response and this will be subject to on-going monitoring.
11. The inspection team considers the patient information leaflets are unclear in some areas. There is also inconsistency between information regarding the day on which a pregnancy test should be performed after the IUI procedure. SLC T58.	The PR should review the centre's patient information leaflets to ensure that the information provided is clear and consistent. A summary of the review and corrective action identified and implemented should be submitted to the centre's inspector by 23 April 2014.	Patient information leaflets are being revised and all the imconsistency are corrected. A summary of the review and corrective action identified and implemented will eb submitted to the centre's inspector by 23rd of April 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
12. The centre does not have procedures in place to ensure that records are kept for at least 30 years.	The PR should ensure that records are kept for at least 30 years (or for such longer period as may be specified in	The centre has in place a procedure to ensure that the rrecords are kept for 30 years. A typo in the audit report was	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

An audit report reviewed on inspection stated that patient notes are retained for 25 years. SLC T48.	Directions) after clinical use, or the expiry date. Evidence of this could include documentation of the requirement in the centre's records management policy and staff training. Evidence to be submitted to the centre's inspector by 23 April 2014.	missed. Centre's records management policy is currently being reviewed. Evidence of staff training and the summary of the review will be submitted to the centre's inspector by the 23rd April 2014.	
13. The centre did not submit an annual return for IUI treatments for 2012 to the Authority. General Direction 0005.	The PR should ensure that annual returns for IUI treatment are submitted to the HFEA within the required timeframes.	In future the submission of the annual return for the IUI treatents will be submitted within the prescribed period.	Since the inspection, annual returns have been submitted for both 2012 and 2013. The 2013 return was submitted within the required timeframe. No further action is required.
14. Payment of the invoice for HFEA annual fees provided to the centre in July 2013 remained outstanding at the time of inspection. This invoice has subsequently been paid. SLC T9d.	The PR should ensure that fees are paid to the Authority within the timescale specified in Directions or in writing. The PR should review the processes for payment of fees with the Trust finance department, to identify where there are barriers to timely payment. Confirmation of this review should be submitted to the centre's inspector by 23 April 2014.	I have checked with our finance department who have reassured me that the payment will be made on the 6th of March 2014. I will follow it through next week to ensur ethat hFEA havereceived the payment.	This issue relates to payment of annual fees and not, as the PR's response suggests the renewal of licence fee. The lead inspector reminds the PR that a review of processes for payment of fees should be conducted. Confirmation of completion of this review should be submitted by 23 April 2014.

Reponses from the Person Responsible to this inspection report
I accept the contents of the report and have responded to the 14 concerns. While I hav eresponded to this concerns, it will be the responsibility o fteh new PR for our centre to ensure that they are implemented and corrective action documented.