HFEA Licence Committee Meeting

7 November 2013

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

Minutes – Item 3

Centre 0336 (Simply Fertility) – Initial Treatment (IUI donor/ partner sperm) and Storage Inspection Report

Members of the Committee: Sally Cheshire (lay) Chair Gemma Hobcraft (lay) Bishop Lee Rayfield (lay) (video) Debbie Barber (professional) Andy Greenfield (professional) Committee Secretary: Lauren Crawford	Legal Adviser: Graham Miles, Morgan Cole Observing: Sam Hartley, Head of Governance and Licensing, HFEA Juliet Tizzard, Interim Director of Strategy, HFEA

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

The following papers were considered by the Committee

- Initial inspection report
- Application form
- CV of proposed Person Responsible (PR) (confirmation letter and references not required as proposed PR is the applicant and has been PR before and discharged his duties during that role)
- CV of proposed Licence Holder (LH)
- Confirmation letter from the proposed LH

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that an initial enquiry regarding Simply Fertility was received by the HFEA from the proposed Person Responsible (PR) Mr Andrew Glew in July 2013 and the application for a treatment (insemination using partner/ donor sperm) and storage was received in August.

2. The Committee noted that Simply Fertility is located at:

   Baddow Hospital
   West Hanningfield Road
   Great Baddow
   Chelmsford, Essex
   CM2 8HN

3. The Committee noted that at the time of the inspection, the Inspectorate reported that there was one 'major' and two 'other' non-compliances or areas of practice that required improvement.

4. The Committee noted that since the inspection the proposed PR has provided evidence that one recommendation has been fully implemented. The remaining recommendations are:

   'Major' areas of non-compliance
   - The PR should revise the third party agreement (TPA) with the courier that will distribute gametes on behalf of the centre to include and/ or make reference to the relevant HFEA standards that the courier must need to ensure the safety and security of the gametes during distribution

   'Other' areas of non-compliance
   - The PR should ensure compliance with Standard Licence Condition (SLC) T21 for its diagnostic andrology service by the time of the next inspection either by demonstrating clinical pathology accreditation (which is the current direct equivalent standard) or by being able to provide evidence of having status equivalent to that conferred by CPA

5. The Committee noted the Inspectorate's recommendation to grant the centre's licence for a two year period without additional conditions, subject to the proposed PR implementing the recommendations of this report within the prescribed timescales and to also appoint the proposed PR and Licence Holder (LH).

Discussion

6. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

7. The Committee noted that the proposed PR (Mr Andrew Glew) holds academic qualifications in the field of biological sciences and was previously the PR of licensed centre 0030. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). He has successfully completed the HFEA PR Entry Programme.

8. The Committee was satisfied that the proposed PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended). No references have been supplied along with this application as the PR's history at centre 0030 was seen as sufficient evidence for the Executive.

9. The Committee was satisfied regarding the suitability of the proposed LH, Mr Subrata Gangooly.

10. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

11. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

12. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [the Committee] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

13. The Committee noted the Inspectorate's recommendation for a two year licence, without additional conditions, subject to the proposed PR implementing the recommendations of this report within the prescribed timescales.

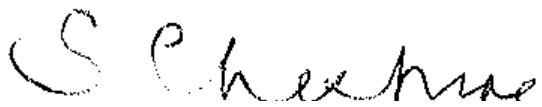
Decision

14. The Panel agreed to appoint Mr Andrew Glew as the Person Responsible for Simply Fertility (Centre 0336) with immediate effect, in accordance with section 18A of the HFE Act 1990 (as amended).

15. The Panel agreed to appoint Mr Subrata Gangooly as the Licence Holder for Simply Fertility (Centre 0336) with immediate effect.

16. The Committee agreed to grant the centre's licence for a period of two years with no additional conditions, subject to the proposed PR implementing the recommendations of this report within the prescribed timescales.

Signed: Date: 21/11/2013



Sally Cheshire (Chair)

Initial Licence Inspection Report

Date of Inspection: 24 September 2013
Purpose of inspection: New 'Treatment (insemination using partner/donor sperm) and Storage' Licence
Length of inspection: 6 hours
Inspectors: Parvez Qureshi, Debra Bloor

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the new licence application.

Date of Licence Committee: 7 November 2013

Purpose of the Inspection report
The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

The purpose of the inspection is to assess whether a centre applying for a new licence will have in place processes and procedures to ensure that they will comply with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC) to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application

Centre details - proposed

Centre Name	Simply Fertility
Centre Number	0336
Centre Address	Baddow Hospital, West Hanningfield Road, Great Baddow, Chelmsford, Essex CM2 8HN
Person Responsible	Mr Andrew Glew
Licence Holder	Mr Subrata Gangooly
Proposed date of licence issue	Subject to Licence Committee decision on 7 November 2013

Contents

Report to Licence Committee

Brief description of the centre:

An initial enquiry was received by the HFEA from Mr Andrew Glew the proposed Person Responsible (PR) on 15 July and a new treatment and storage application on 29 August 2013. Subject to approval by the Licence Committee on 7 November 2013, it is anticipated the centre will become operational by December 2013.

Simply Fertility is located within Baddow Hospital. The centre will comprise of an office, a male production room, a laboratory, three treatment rooms and a scanning room. The centre also will have access to a number of consultation rooms as required.

The centre will act as a secondary satellite IVF provider for Herts and Essex Fertility Centre (centre 0030).

The centre plans to provide intra uterine insemination (IUI) and donor insemination (DI) treatment to privately funded patients. The centre has been designed to carry out 400 treatments per year.

Proposed activities of the Centre:

Type of treatment	Number of treatment cycles premises designed to accommodate
IUI/DI	400

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

Summary for licensing decision:

The proposed PR has submitted documentation to satisfy the requirements of General Direction 0008 - Information to be submitted to the Human Fertilisation and Embryology Authority as part of the licensing process. These documents have been reviewed by the inspection team and are compliant (with the exceptions detailed within this report) with CoP requirements.

The centre has submitted an application fee to the HFEA.

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to and after the inspection, and from observations and interviews conducted during the inspection visit, to conclude that:

- The proposed PR satisfies the requirements of section 16 of the HF&E Act 1990 (as amended) necessary for a licence to be granted since:
    1. The proposed PR is the applicant for this 'Treatment (insemination using partner/donor sperm) and Storage' Licence.
    2. The proposed PR has academic qualifications in biological sciences. The proposed PR also has more than two year's practical experience which is directly relevant to the activity to be authorised by the licence.
    3. The proposed PR has previously completed the PR entry programme (certificate number T/1191/8) and was, until recently, the PR at HFEA licensed centre 0030 and he was considered to have discharged his duties during that role. In view of this new references were not obtained. The proposed PR has also recently completed the new version of the programme (certificate number T/1251/81).

- The proposed PR is expected to discharge his duty under section 17 of the HF&E Act 1990 (as amended).

- The initial 'Treatment (insemination using partner/donor sperm) and Storage' Licence application details the appointment of a Licence Holder (LH). The proposed LH's curriculum vitae has been submitted together with a confirmation that he is willing to assume this responsibility.

- The premises and equipment are suitable:
    - At inspection, the premises appeared appropriate for the proposed licensable activities and should provide a safe, clean and private environment both for patients and donors, their gametes and centre staff. The inspection team considered the premises to be suitable both on the basis of observations and in consideration that the centre is located within a CQC registered hospital.

      The centre has suitable clinical and laboratory equipment. This equipment has been commissioned and validated.

      The air quality in the laboratory was tested on 20 September 2013 and achieved at least grade C in the critical processing areas and grade D background air.

These air quality results meet the requirements of Standard Licence Condition (SLC) T20.

- The proposed practices and processes are anticipated to be suitable:
  The centre has documented standard operating procedures (SOPs) for the proposed licensed activities and activities carried out in connection with the provision of licensed treatment. Critical processes have been validated.

  All staff provided evidence that they are suitably qualified and experienced to carry out their designated jobs and the PR described appropriate plans to ensure that staff competence to perform their designated roles will be effectively monitored and reviewed once activity is commenced.

  The centre has documented quality indicators (QIs) and will establish monitoring and audit programmes which will allow the PR to identify whether processes are being effectively implemented and that practices are suitable.

The Licence Committee is asked to note that recommendations were made in relation to one major area for improvement and two "other" areas for improvement and since the inspection visit the centre has provided evidence that the following recommendation has been fully implemented:

"Other" recommendation for improvement

- The proposed PR should ensure that the centre's website meets the requirements of the Chair's Letter CH (11)02.

Since the inspection, the proposed PR has given a commitment to fully implement the following recommendations:

Major recommendation for improvement

- The PR should revise the third party agreement (TPA) with the courier that will distribute gametes on behalf of the centre to include and/or make reference to the relevant HFEA standards that the courier must meet to ensure the safety and security of gametes during distribution;

"Other" recommendation for improvement

- The PR should ensure compliance with SLC T21 for its diagnostic andrology service by the time of the next inspection either by demonstrating clinical pathology accreditation (CPA), ISO 15189 accreditation (which is the current direct equivalent standard) or by being able to provide evidence of having status equivalent to that conferred by CPA.

Recommendation to the Licence Committee:

The inspection team considers that, overall; there is sufficient information available to recommend:

1. Granting a treatment (insemination using partner / donor sperm) and storage licence for a period of two years without additional conditions, subject to the proposed PR implementing the recommendations of this report within the prescribed timescales.

2. Appointment of the proposed Person Responsible.

3. Appointment of the proposed Licence Holder.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- 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
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the proposed centre does well. **Witnessing (Guidance Note 18)** The centre has an SOP in place for the process to be followed when carrying out witnessing checks (SLC T33(b)). Discussions with laboratory staff demonstrated that processes will be in place to double check the identification of samples, patients and sperm donors to whom they relate at all critical points of the clinical and laboratory processes. The witnessing SOP specifies that witnessing checks will be completed and documented appropriately at the time the procedures take place (SLC T71). The centre has established QIs relevant to witnessing. An audit schedule has been developed and will become effective on commencement of service (SLC T35 and T36). Laboratory staff were not able to provided documented evidence of the assessment of their competence in witnessing (SLC T15a). Since the inspection visit the proposed PR has provided evidence of this assessment.
What the proposed centre could do better. Nothing noted.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the proposed centre does well.

Donor recruitment, assessment and screening (Guidance Note 11)
The centre has an SOP which documents the clinical processes to be followed for recruiting sperm donors (SLC T33b). Discussion with staff and a review of the information submitted for the inspection showed that donors will be selected on the basis of their age, health and medical information provided during consultation (SLC T52(a)). All screening will be undertaken in accordance with current professional guidelines and carried out by a laboratory which is CPA accredited (SLC T53a). Procedures were in place to identify when additional screening tests may be required (SLC T52g).

The proposed PR reported that the centre is considering recruitment of egg sharers donating for treatment purposes and this will be conducted via a satellite arrangement with HFEA licensed centre 0030.

The centre has established QIs relevant to donor recruitment, assessment and screening. An audit schedule has been developed and will become effective on commencement of service (SLC T35 and T36).

Payments for donors (Guidance Note 13)
Staff were aware that payments to donors are restricted to the limits prescribed in Directions 0001 and a log of both excess expenses incurred by donors and the amount reimbursed to them will be maintained by the centre.

Donor assisted conception (Guidance Note 20)
Patients will be informed of the importance of informing any child at an early age that the child results from the gametes of a person who is not their parent and patients will be provided with information on how to inform the child (SLC T63).

Laboratory staff were not able to provide documented evidence of the assessment of their competence in selecting and recruiting sperm donors (SLC T15a). Since the inspection visit the proposed PR has provided evidence of this assessment.

What the proposed centre could do better.

Nothing noted.

Patient selection criteria and laboratory tests
- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the proposed centre does well.

Procuring, processing and transporting gametes (Guidance Note 15)
All critical procurement and processing procedures are documented in SOPs (SLC T33b). The proposed PR reported that justification for the use of gametes in treatment will be based on the patient's medical history and therapeutic indications and this will be documented in patient notes (SLC T49).

Prior to processing, the providers of gametes intended for use in treatment or storage will be screened for HIV, Hepatitis B and Hepatitis C and additional testing, including for HTLV-1, will be carried out when required (SLC T50 c/d). The screening tests will be performed by a CPA accredited laboratory (SLC T21 and T51).

The PR confirmed that in the event of sperm being produced off-site then a record of this will be retained in the patient's notes (SLC T68).

The centre had not established QIs for procurement and processing procedures (SLC T35). Since the inspection visit the proposed PR has provided evidence that they have been established.

Counselling (Guidance Note 3)
There is an appropriate counselling SOP in place (SLC T33b). Counselling will be offered to patients as required by schedule 3 and schedule 3ZA of the HF&E Act 1990 (as amended). Implications counselling is mandatory for sperm donors and recipients and the cost of this will be included in the treatment costs.

The counsellors will be able to offer appointments at the centre or off-site. If required, the counsellors will be able to refer patients and donors to specialist genetic counsellors (CoP Guidance Note 3.10). Counselling notes will be kept secure and separate from the main medical notes (CoP Guidance Note 3.12).

In surrogacy arrangement (provided under the terms of the satellite agreement with another HFEA licensed centre) counselling will be offered to all parties in the arrangement.

An audit schedule for counselling has been developed and will become effective on commencement of service (SLC T36).

QIs for counselling had not been established (SLC T35). Since the inspection visit the proposed PR has provided evidence that they have been established.

What the proposed centre could do better.

Procuring, processing and transporting gametes (Guidance Note 15)
The centre was not able to demonstrate accreditation to a standard equivalent to CPA for diagnostic semen analysis (SLC T21). See recommendation 2.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the proposed centre does well.

Quality management system (QMS) (Guidance Note 23)
This consists of a quality manual, SOPs and associated documents (SLC T33).

There are SOPs for all activities that the centre wishes to include on the licence and for those activities carried out in the course of providing treatment services that do not require a licence (SLC T33b). These SOPs detail the specifications for critical materials and reagents (SLC T31).

The PR provided assurances that an annual review of the QMS will be conducted to ensure continuous and systematic improvement (HF&E Act 1990 (as amended), Schedule 3A (10)).

The centre had not established QIs for some of the licensed activities. Since the inspection visit the proposed PR has provided evidence that these have been established and the centre has developed an audit schedule which will become effective on commencement of service (SLC T35 and T36).

Traceability (Guidance Note 19)
The centre will have a process in place to ensure all gametes (sperm samples) are traceable from procurement to use (SLC T99). There is an SOP to ensure traceability of gametes, consumables and equipment (SLC T22, T99 and T102) and to ensure the accurate identification of patients' and donors' gametes (SLC T100). Containers will be appropriately labelled (SLC T101).

The centre has established QIs relevant to traceability and an audit schedule has been developed and will become effective on commencement of service (SLC T35 and T36).

Laboratory staff were not able to provide documented evidence of the receipt of training in traceability procedures (T15a). Since the inspection visit the proposed PR has provided evidence that this has been addressed.

Process Validation (Guidance Note 15)
Validation of critical procurement and processing procedures has been completed (SLC T72).

Equipment and materials (Guidance Note 26)
Activities will be carried out using equipment designed for the purpose (SLC T23). All new

equipment is currently under warranty and so maintenance conrtacts were not in place at the time of the inspection however, reassurance was provided by laboraory staff that servicing agreements will be established. Equipment will be regularly inspected and maintained. Evidence of validation of a centrifuge and the flow hood was reviewed during the inspection. At the time of the inspection, the proposed PR confirmed that the centre was awaiting delivery of three dewars, low oxygen and nitrogen alarms and a dry shipper. (SLC T24). Since the inspection visit the proposed PR has provided evidence that this equipment has been installed, commissioned and validated (SLC T24). There are documented procedures for the operation of critical equipment and there is a contingency plan with another HFEA licensed centre in place if the equipment malfunctions or fails (SLC T27).

Equipment with a critical measuring function has been appropriately calibrated against a traceable standard (SLC T24). Verbal reassurance was provided by the the PR that wherever possible, CE marked consumables will be used (SLC T30).

Premises (Guidance Note 26)
The inspection team considered the premises to be suitable both on the basis of observation and in consideration that they are located within a CQC registered hospital (SLC T17). The main entrance has secure access arrangements and rooms where records and gametes will be be kept have secure access.

Review of documents and discussions with the laboratory staff demonstrated that the processing of gametes (sperm samples) will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality (SLC T20).

Adverse incidents (Guidance Note 27)
The centre has a documented procedure for reporting adverse incidents to the HFEA (SLC T118). Staff were able to describe the process to be followed for reporting and the investigation of an incident and demonstrated a good understanding of the nature of incidents that would be reported to the HFEA within the required timeframe.

Third Party agreements (Guidance Note 24)
TPAs are in place with all suppliers that will provide goods or services that will influence the quality and safety of gametes (SLC T111) and a list is maintained of all TPAs (SLC T115). Five TPAs were audited for compliance against regulatory requirements, and with some exceptions, these comply with SLC T113, T114 and T116.

The application form indicates that the centre will act as secondary Satellite IVF provider for Herts and Essex Fertility Centre (0030). The proposed PR stated that a third party agreement was being formalised with centre 0030 for this.

What the proposed centre could do better.

Third Party agreements (Guidance Note 24)
A review of five TPAs showed that their content was not specific to the service to be provided by the third parties (SLC T114d, e and f) and the PR was advised to review the

TPAs with the courier service that will distribute gametes and with the diagnostic laboratory. Since the inspection visit the proposed PR has provided evidence that the TPA with the testing laboratory has been amended to reference the requirements with which the third party must comply and that the courier has been provided with guidance on some of the required standards. It remains the opinion of the inspection team that the TPA with the courier requires further revision to ensure that the third party is aware of the standards (as referenced in HFEA SLCs) that must be met as part of the agreement. See recommendation 1.

Multiple Births (Guidance Note 7)

What the proposed centre does well.

Not applicable to this centre because they will be an IUI/DI centre only.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the proposed centre does well.

Person Responsible (Guidance Note 1)
The proposed PR has academic qualifications in the field of biological sciences as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The proposed PR has successfully completed the HFEA PR Entry Programme (PREP number T/1251/81).

Staff (Guidance Note 2)
An organisational chart is in place which defines accountability and reporting relationships (SLC T11).

The centre will have access to a registered medical practitioner who will be able to advise on and oversee the medical activities (SLC T16) and Health Care Professions Council registered clinical scientists.

The PR confirmed that all staff that will be working under the auspices of the licence are qualified and suitable persons to participate in the activities to be authorised by the licence (HF&E Act 1990 (as amended) section 17 (1) (a)).

Key staff at the centre will consist of an accredited consultant, a senior embryologist (PR and quality manager), laboratory manager, nurse co-ordinator and a senior counsellor. All key staff are registered with their respective professional bodies (SLC T14).

The proposed PR considered that the current number of staff will be adequate for the volume of work that would be undertaken by the centre (SLC T12). Staff will participate in relevant professional development by attending training courses and meetings.

The centre has developed a formal induction training programme but documented evidence of this for all staff was not made available for the inspection (SLC T15a). Since the inspection visit the proposed PR has provided evidence of this.

The proposed PR confirmed that all staff are competent in their designated tasks. However, staff were not able to provide documented evidence of the assessment of their competence in their designated roles (SLC T12 and T15a). Since the inspection visit the proposed PR has provided evidence that this non-compliance has been addressed.

What the proposed centre could do better.

Nothing noted.

Welfare of the Child (Guidance Note 8)

What the proposed centre does well.

Welfare of the Child (Guidance Note 8)
There is an SOP in place for the process to be followed when carrying out a welfare of the child (WoC) assessment (SLC T33(b)). Account will be taken of the welfare of any child who may be born as a result of treatment, and of any other child who may be affected by the birth, before treatment is provided (SLC T56). If asked for an opinion, the counsellor will be able write a report with the consent of the patient.

The centre has established QIs relevant to assessing the WoC. An audit schedule has been developed and will become effective on commencement of service (SLC T35 and T36).

Clinical staff were not able to provided documented evidence of the assessment of their competence to carry out a WoC assessment (SLC T15a). Since the inspection visit the proposed PR has provided evidence that this non-compliance has been addressed.

What the proposed centre could do better.

Nothing noted.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the proposed centre does well.

Treating patients fairly (Guidance Note 29)
The centre has policies in place on treating patients fairly, which will ensure all licensed activities are conducted in a non-discriminatory manner.

Complaints (Guidance Note 28)
There is a complaints procedure in place, and a log of complaints will be maintained (CoP Guidance Note 28).

Provision of costed treatment plans (Guidance Note 4)
A review of the centre's personalised costed treatment plan showed that its content was not compliant with requirements (CoP Guidance 4.3). Since the inspection visit the proposed PR has provided evidence that this has been addressed.

Egg sharing arrangements (Guidance Note 12)
The proposed PR advised that the centre will act as a secondary Satellite IVF provider and through this arrangement will be offering egg sharing service in conjunction with HFEA licensed centre 0030. A discussion with the proposed PR and a review of centre's egg sharing documents showed that the centre's processes will be compliant with requirements.

Surrogacy (Guidance Note 14)
The proposed PR stated that the centre will act as a secondary Satellite IVF provider and through this arrangement will be offering treatment involving surrogacy in conjunction with HFEA licensed centre 0030. A discussion with the proposed PR and a review of centre's surrogacy documents showed that the centre's processes will be compliant with requirements.

What the proposed centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about legal parenthood (Guidance Note 6)

What the proposed centre does well.

There are SOPs for providing information to patients and sperm donors (SLC T33b). Patient information was provided prior to the inspection and was considered to be comprehensive. The patient information was audited against SLC T58, T63 and the relevant guidance notes and was found to be broadly compliant.

What the proposed centre could do better.

A review of the information on the centre's website was conducted and was found to be non-compliant with HFEA guidance. The website, which references data for HFEA licensed centre 0030, does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type (Chair's Letter CH (11)02). See recommendation 3.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the proposed centre does well.

The centre has proposed procedures to ensure that consent is obtained before gametes are used in treatment or stored (SLC T57). Consents will be kept in the patient's records (SLC T46f). There is an SOP for taking consent (SLC T33b), and an audit schedule for consent has been developed and will become effective on commencement of service (SLC T36). The identity of the person providing consent will be verified by comparison with photographic evidence and referenced to notes (CoP Guidance Note 5.10).

Consent to legal parenthood will be obtained where required and centre staff were aware of this. The centre will have a procedure in place to ensure that where a patient or second parent withdraws consent, the second parent or patient will be informed and in the case of the patient this will be before treatment takes place (SLC T64 and T65).

The centre's SOP for obtaining relevant written records of consent to parenthood did not accurately reflect the requirements for taking consent to parenthood before treating a woman with donor sperm (SLC T33b). Since the inspection visit the proposed PR has provided evidence that this has been addressed.

What the proposed centre could do better.

Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- 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
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

The centre will be conducting the activities essential to the provision of licensed activities at the licensed premises only (SLC T1).

Staff are aware of the requirements of General Directions 0001 in respect of compensation for gamete donors and were able to demonstrate that they have proposed procedures that should ensure compliance with the Directions when implemented.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

The centre has a procedure documenting the process to be followed when storing gametes (SLC T33(b)). Patients and donors will be appropriately screened before their gametes are stored (SLC T50 and T52).

The centre has proposed systems that will ensure that gametes are stored within the terms of the consent of the gamete providers and in line with the relevant statutory storage periods. The centre has established QIs relevant to storage and an audit schedule has been developed and will become effective on commencement of service (SLC T35 and T36).
What the centre could do better. Nothing noted.

Distribution and / or receipt of gametes and embryos • Distribution of gametes and embryos (Guidance Note 15) • Export of gametes and embryos (Guidance Note 16) • Receipt of gametes and embryos (Guidance Note 15) • Import of gametes and embryos (Guidance Note 16)
What the proposed centre does well. There is an SOP in place for the distribution, receipt, and recall of gametes (SLC T105, T106, T107, T108, T109 and T110) that will ensure compliance with HFEA requirements for distribution of gametes with one exception (see comments in section above on third party agreements).
What the proposed centre could do better. Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the proposed centre does well.

Documents submitted for the inspection and those reviewed at the time of the inspection are version controlled, with version numbers and review dates (SLC T34). The content of patient records as required by SLC T46 was discussed with the proposed PR who provided assurances that the required elements will be included.

Procedures are in place to ensure that records are protected from unauthorised access and amendment (SLC T47). These measures include secure notes storage and password protection on the computers. Records will be held for a minimum of 30 years and there is the facility to hold records for longer where circumstances require (SLC T48, T103 and T104).

What the proposed centre could do better.

Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the proposed centre does well.

The centre did not have an SOP for submitting data to the HFEA (SLC T33b). The proposed PR stated staff were familiar with submitting data to the HFEA but relevant staff were not able to provided documented evidence of the assessment of their competence for submitting data (SLC T15a). Since the inspection visit the proposed PR has provided evidence that this has been addressed.

What the proposed centre could do better.

Nothing noted.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the proposed centre does well.

Confidentiality and privacy (Guidance Note 30)
Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that all information will be kept confidential and only disclosed in circumstances permitted by law. The centre has processes in place to ensure that access to the centre's health data and records will be kept secure at all times and is only available to centre staff named on the centre's licence or authorised by the PR (SLC T43; T44 & T45).

The inspection team considered that there is good provision for maintaining the confidentiality and privacy of patients and donors. Patients and donors will be identified by reference to their photographic identification and a copy of their photographic identification will be retained in their notes.

Computers are password protected and paper records will be stored securely on the premises. Access to critical areas is restricted by key pad locks and/or key operated locks.

Disclosure of information, held on the HFEA Register, for use in research
The centre has procedures in place that are expected to ensure that they seek consent from relevant parties to the disclosure of information held on the HFEA register to medical or other researchers.

What the proposed centre could do better.

Nothing noted.

Areas of proposed practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area 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. 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	Proposed 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	Proposed PR Response	Executive Review
1. The TPA with the courier that will distribute gametes on behalf of the centre does not reference all of the standards (as referenced in HFEA SLCs) that must be met as part of the	It is acknowledged that the centre will not be undertaking distribution of gametes immediately and the improvements required to this TPA does not therefore represent an immediate risk.	Our third party agreement with couriers states that they must be aware and abide with the suggestions from Alert 21. A full copy of Alert 21 is attached to the current	The lead inspector considers this to be an acceptable response. The proposed PR to inform the centre inspector on completion

agreement. SLC T114	The PR should revise the TPA to include and/or make reference to the relevant HFEA standards that the courier must meet to ensure the safety and security of gametes during distribution. A copy of the revised TPA should be provided to the HFEA before any distribution takes place. In responding to this report, the proposed PR should provide confirmation that no distribution will be undertaken before a copy of the revised TPA is forwarded to HFEA.	TPA. I understand that the inspectors felt this was not sufficient as there was no action to require that the third party does follow all the recommendations. We agree that we will re-write the TPA and that no gamete transport will occur until that time.	of this action. Further action required.

‘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	Proposed PR Response	Executive Review
2. The centre was not able to demonstrate accreditation to a standard equivalent to CPA for diagnostic semen analysis (SLC T21).	It is acknowledged that the centre may need to be operational to demonstrate compliance with SLC T21. In consideration of this, the PR should ensure compliance with SLC T21 by the time of the next inspection either by demonstrating clinical pathology accreditation, ISO 15189 accreditation (which is the current direct equivalent standard) or by being able to provide evidence of having status equivalent to that conferred by CPA.	We will be able to demonstrate equivalent status for CPA by providing evidence of the following: I. We will have an HFEA approved a QMS II. We will use validated procedures for semen analysis; III. Our staff will be appropriately qualified to perform and interpret semen assessments (as demonstrated by completion of	The lead inspector considers this to be an acceptable response. The proposed PR to inform the centre inspector on completion of this action. Further action required.

		the ACE certificate and HPC registration), IV. Participation in the NEQAS scheme for andrology services. This we will achieve as soon as we can demonstrate the strength of our QMS, as every other aspect of the requirements are already in place.	
3. A review of the information on the centre's website was conducted and was found to be non-compliant with HFEA guidance. The website, which references data for HFEA licensed centre 0030, does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type (Chair's Letter CH (11)02).	The proposed PR should ensure that the centre's website meets the requirements of the Chair's Letter CH (11)02. 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.	We do not have any other results other than those published from the primary centre website. We have made it clear that as soon as we have our own results we will publish them. In the meantime we have provided the results for different age groups and placed a link to the HFEA results page for centre 0030. We believe that this meets the requirements of the Chairs letter.	The lead inspector notes the PR's response and a review of the centre's website meets the requirements of the Chair's Letter CH (11)02. No further action required.

Additional information from the Person Responsible
We look forward to hearing from the license committee following our in depth inspection. We are happy with the report and understand the actions still required. We look forward to working with the authority to ensure that this centre is a compliant centre, fulfilling the needs of our patients and donors as well as the regulatory requirements.