Inspection Report

Date of Inspection: 28 February 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 8 hours
Inspectors: Vicki Lamb
Janet Kirkland

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 3 March 2010 and 18 May 2012.

Date of Executive Licensing Panel: 1 June 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Andrology Solutions
Centre number	0293
Licence number	L0293/2/c
Centre address	55 Wimpole Street London W1G 8YL
Person Responsible	Dr Sheryl Homa
Licence Holder	Ms Sara Matthews
Date licence issued	1 August 2008
Licence expiry date	31 July 2012

Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

Andrology Solutions provides intrauterine insemination (IUI) treatment, with both partner and donor sperm, to private patients. They also provide sperm storage facilities. The centre has been licensed since 2007.

Dr Sheryl Homa has been PR at the centre since the inception of the centre and has completed her HFEA PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 February 2011 – 31 January 2012*
Donor insemination (DI)	14
Partner insemination	190**

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

Outcomes*
For the year 2010 the centre reported 190 cycles of partner insemination with 28 pregnancies. This equates to a 15% pregnancy rate which is consistent with the national average.

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

** For the calendar year 2010

Summary for licensing decision

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

- the PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that the following recommendations have been fully implemented:

Other areas of practice that require improvement:

- The centre should perform their own welfare of the child assessments when a patient who has had treatment elsewhere attends for treatment at the centre, even though the welfare of the child assessment has been performed at the previous treatment centre.
- The donor information should be changed to include the importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made.
- Some of the patient information should to be corrected to make it relevant for patients rather than donors.
- Where consent to legal parenthood is completed at another centre, the PR must ensure that prior to treatment being given, there is a mechanism in place to ensure that consent to legal parenthood by either party has not been varied or withdrawn.

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

Other areas of practice that require improvement:

- The PR should review the information on their website and update the information as required to ensure it is compliant with Chair's letter CH(11)02.

The Executive Licensing Panel is asked to note that there are no areas of practice that still require improvement.

Recommendation to the Executive Licensing Panel:

The inspection team considers that overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

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 centre does well. Evidence was seen at the time of inspection that the identification of samples and the patients to whom they relate are witnessed by two members of staff at all critical points of the laboratory process. This witnessing is performed at the time the procedure is performed and a record of the witnessing is kept in each patient's records (Standard Licence Condition T71). The requirement for witnessing is detailed in a standard operating procedure (SOP) (Standard Licence Condition T33b). Witnessing procedures have been audited against compliance with the centre's SOPs (Standard Licence Condition T36). No non-conformities were identified. All staff are considered by the PR to be competent to carry out witnessing (Standard Licence Condition T15a). All five patient records reviewed during the inspection contained evidence of witnessing being completed at all critical stages of processing and treatment.
What the 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 centre does well.

Procuring and processing procedures are documented in SOPs (Standard Licence Condition T33b). These procedures have been validated (Standard Licence Condition T72).

Prior to partner insemination treatment, patients are not screened for HIV, Hepatitis B and C, but centre staff were able to demonstrate that the risk of cross contamination and staff exposure had been addressed through the use of appropriate procedures and practices (Standard Licence Condition T50 and European Commission Directive 2006/17/EC Annex III, 2.2).

Investigation results and reports demonstrated that prior to storage of sperm, patients are screened for HIV, Hepatitis B and C and HTLV (Standard Licence Condition T50) by a Clinical Pathology Accreditation (CPA) accredited laboratory (Standard Licence Condition T51). This centre does not store samples from patients who have tested positive for HIV, Hepatitis B or C, but they are able to refer patients to centres who do store these samples.

Diagnostic semen analyses are performed in a CPA accredited laboratory (Standard Licence Condition T21). The certificate demonstrating this was provided on the inspection.

Quality indicators in relation to processing procedures have been set, (Standard Licence Condition T35). An audit schedule is in place for auditing procurement and processing procedures. Audits have been performed and corrective actions have been documented and implemented (Standard Licence Condition T36).

An audit of four patient records documented evidence that the clinician responsible for the patient has provided written justification for the use of their gametes based on the patient's medical history and therapeutic indications. (Standard Licence Condition T49). Each record contained a patient identification, how they were identified, medical and social history, welfare of the child assessment, consent, investigations and laboratory test results and what treatment was provided to them (Standard Licence Condition T46). The identity of patients are confirmed by checking their passports. Copies of passport photographs were seen in patient records.

Counselling is offered to patients as required by schedule 3 of HF&E Act 1990 (as amended). The centre's counsellor is appropriately qualified and has submitted an application for accreditation under the British Infertility Counselling Association accreditation scheme. Counselling SOPs are available (Standard Licence Condition T33b) and the counsellor is able to refer patients for specialist counselling if required.

What the 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 centre does well.

Sperm donors who are known to the recipients donate samples for use at this centre. These known sperm donors are screened appropriately (Standard Licence Condition T52) and are registered with the HFEA as donors. No reimbursements have been made to the known donors (General Directions 0001).

Gender reassignment patients who choose to store their sperm for possible future use, possibly requiring the use of a surrogate, are appropriately screened as donors (Standard Licence Condition T52).

Screening is performed by a CPA accredited laboratory (Standard Licence Condition T53).

The centre does not recruit identifiable sperm donors at present but there are protocols in place should they decide to do so (Standard Licence Condition T33b). Donor sperm is obtained either from HFEA-licensed donor sperm banks in the UK or is imported from outside the UK under General Directions 0006.

Patients are informed of the importance of telling a child of its genetic origins at an early age (Standard Licence Condition T63).

What the centre could do better.

Nothing noted

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 centre does well.

The PR provided information and evidence to show that the centre follows good clinical practice and has suitable premises and equipment for the treatment services offered.

Quality management system: Guidance Note 23
Staff provided documented evidence to show that the centre has a quality management system including a quality manual, SOPs, records of quality indicators and audits carried

out to continually improve the quality and effectiveness of the service it provides in accordance with good practice (Standard Licence Condition T33 and T35). Document control was seen to be in place (Standard Licence Condition T34).The audit schedule runs over a two year period. Evidence of the documentation and implementation of corrective actions was seen (Standard Licence Condition T36). An annual management review is undertaken where the results of the audits are reviewed.

Traceability: Guidance Note 19
Staff at the centre provided evidence to show that all gametes are traceable from procurement to patient treatment or disposal. (Standard Licence Condition T99). The centre has also established and implemented documented procedures (Standard Licence Condition T33b) to ensure that all relevant material coming into contact with gametes, and equipment used in the processing of gametes, is traceable. (Standard Licence Condition T99). All containers used during processing for treatment or storage are appropriately labelled (Standard Licence Condition T101).

Validation: Guidance Note 15
The critical processing procedures have been validated to ensure they do not render the gametes clinically ineffective or harmful to the recipient (standard Licence Condition T72). Equipment used at the centre has been appropriately validated (Standard Licence Condition T24).

Equipment and materials: Guidance Note 26
Observation and documented evidence demonstrated that all instruments and equipment used for the procurement and processing of gametes are of good quality and regularly maintained (Standard Licence Condition T28). Medical devices used are CE marked. (Standard Licence Conditions T30). Staff provided evidence to demonstrate that all critical equipment has been validated (Standard Licence Condition T24). Documented records were seen of the regular servicing, cleaning and disinfection of equipment (Standard Licence Conditions T23 and T26). All equipment or materials that affect critical processing were observed to be subject to monitoring, alerts, alarms, and verbal confirmation was provided that equipment with a critical measuring function are calibrated against traceable standards (Standard Licence Condition T24). Documented procedures are available in the laboratory for the operation of all critical equipment (Standard Licence Condition T27).

Premises – suitability of the premises and air quality: Guidance Note 25
A tour of the premises and evidence provided by staff confirmed that the premises are suitable for the licensed activities (Standard Licence Condition T17). Up to date records showed a regular programme of cleaning (Standard Licence Condition T26). Premises appeared to be clean at the time of inspection. Staff provided documented evidence that regular air quality monitoring is performed and that the processing of gametes takes place in an environment of at least grade C air quality against a background air quality of at least grade D, in compliance with Standard Licence Condition T20. There was appropriate secure access to the premises and to rooms within the premises. All licensed premises are in the same building.

Adverse Incidents: Guidance Note 27
There is an adverse incidents reporting procedure at this centre (Standard Licence Condition T118). No laboratory or clinical incidents have been reported to HFEA since the last inspection, and a review of the adverse incidents records demonstrated that no reportable incidents have occurred at the centre (Standard Licence Condition T120).

Third party agreements: Guidance Note 24
Centre staff have established written agreements with third parties who provide goods or services that influence the quality and safety of gametes, copies of which were provided to the inspector at the time of inspection (Standard Licence Conditions T111). Five third party agreements were reviewed and all five demonstrated that the agreements comply with Standard Licence Condition T114 and that it is a condition of all agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the Code of Practice (Standard Licence Condition T116).

What the centre could do better

Nothing noted

Staff engaged in licensed activity

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

What the centre does well.

The 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 PR has successfully completed the HFEA Person Responsible Entry Programme (certificate number T/1138/7).

The Licence Holder (LH) is a registered medical practitioner and oversees all medical activities at the centre.

The PR is registered with the Health Professions Council and the LH is registered with the General Medical Council (Standard Licence Condition T14). No nurses work at the centre and the andrologists do not qualify for registration with the Health Professions Council.

The PR provided evidence to demonstrate there are sufficient staff in the centre who are suitably qualified and competent for the tasks they perform and that the competency of the each member of staff is assessed (Standard Licence Condition T12). Documented evidence of competency assessments was seen for one member of staff. The assessments covered all aspects of her duties at the centre (Standard Licence Condition T15b). Evidence was provided to demonstrate that staff receive induction training when joining the centre (Standard Licence Condition T15). Staff provided evidence of their qualifications and continuing professional development in their relevant field.

What the centre could do better

Nothing noted

Welfare of the Child (Guidance Note 8)

What the centre does well.

The PR provided documented evidence to show that patients are not provided with treatment until account has been taken of the welfare of any child who may be born as a result and of any other child who may be affected by the birth (Standard Licence Condition T56).

There is a SOP which describes the process to be followed when assessing welfare of the child (Standard Licence Condition T33b).

Quality indicators have been set and an audit of welfare of the child procedures has been performed (Standard Licence Condition T35 and T36). Corrective actions have been documented and implemented.

An audit of three patient records showed that both the patient and their partner had completed welfare of the child assessment questionnaires.

What the centre could do better

Currently the centre does not repeat the welfare of the child assessment where this has been conducted by another centre where the patient had treatment. The centre should perform their own welfare of the child assessments when a patient who has had treatment elsewhere attends for treatment at the centre, even though the welfare of the child assessment has been performed at the previous treatment centre (Standard Licence Condition T56).

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)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)

What the centre does well.

Treating patients fairly: Guidance Note 29
From the evidence provided staff at the centre ensure that all licensed activities are provided in suitable premises and conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients.

Confidentiality and privacy: Guidance Note 30
The PR provided evidence to demonstrate that the staff ensure that all information is kept confidential and only disclosed in circumstances permitted by law (Standard Licence Condition T43). Patient records are stored in locked filing cabinets in locked administration offices. Access to registers and data is restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures (Standard Licence Condition T45). There is an SOP for confidentiality and privacy (Standard Licence Condition 33b), and staff have signed that they have read and understood this SOP. An audit of confidentiality and privacy has been performed, the results have been documented and corrective actions taken (Standard Licence Condition 36).

Complaints: Guidance Note 28
No complaints about this centre have been received by the HFEA. A review of the complaints log demonstrated that complaints have been successfully resolved locally. There is a complaints procedure which is displayed in the consulting room.

Costed treatment plans: Guidance Note 4
Before treatment is offered staff at the centre provide patients seeking treatment and their partner (if applicable) with a personalised costed treatment plan. This plan is broken down into the various costs that the patients may incur (Code of Practice 4.3).

What the 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 centre does well.

Patient information material was submitted pre-inspection and found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality, consent, legal parenthood and the availability of counselling (Standard Licence Condition T58). There is a checklist of information to be provided to patients that is used to ensure that all patients have been provided with the required information. Patients also sign a declaration to confirm they have received the information.

Information on how to make a complaint and how to contact the counsellor was displayed in the consulting room.

The centre has a website describing the various treatments offered, how to contact the centre and an over view of infertility and patient information leaflets.

There is a schedule of audits, including those for providing information (Standard Licence Condition T36).

What the centre could do better.

Information on the website is not compliant with Chair's letter CH(11)02, as the data presented is more than three years old and it does not state that statistics have limitations as a basis for comparisons.

Information for donors does not include the importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made (Code of Practice 11.24k).

The patient information for donor insemination contained information intended for donors, and not for donor gamete recipient patients. This needs to be corrected to make it relevant for patients.

Consent

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

What the centre does well.

Written consent to treatment is obtained from patients and partners before any form of treatment is provided (Standard Licence Condition T57). This includes consent to legal parenthood. An audit of three patient records at the time of inspection demonstrated that consent to treatment had been provided in all three cases.

There is an SOP for staff at the centre to follow for taking consent from patients (Standard Licence Condition T33b). Centre staff have established an audit schedule that includes the audit of consent forms. The findings of the audit have been documented and corrective actions implemented (Standard Licence Condition T36).

What the centre could do better

The PR may accept consent to legal parenthood forms completed at other centres if the patient has had treatment at that other centre and then requests treatment at centre 0293. Where consent to legal parenthood is completed at another centre, the PR must ensure that prior to treatment being given, there is a mechanism in place to ensure that consent to legal parenthood by either party has not been varied or withdrawn (Standard Licence Condition T64 and T65).

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
- 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.

As far as the inspection team could ascertain, the activities authorised by the licence are carried out only on the premises specified in the licence and under the supervision of the PR (Standard Licence Condition T1). The centre does not recruit identifiable donors, and known sperm donors storing sperm at this centre have not been reimbursed for their expenses by the centre.

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.

There is an SOP for the procedure for the storage of sperm (Standard Licence Condition T33b). This SOP includes the validation of this process (Standard Licence Condition T72 and T75).

Evidence was provided to demonstrate that all material currently in store is within the consented storage period (Standard Licence Condition T79 and T80).

Prior to storage, patients and donors are screened for HIV and hepatitis B and C (Standard Licence Condition T50 and T52). Only samples from patients who have screened negative for HIV and hepatitis B and C are stored at this centre. All screening is performed in a CPA accredited laboratory (Standard Licence Condition T51 and T53).

What the centre could do better

Nothing noted

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)
- Export of gametes and embryos (Guidance Note 16)

What the centre does well.

There is an SOP that covers the circumstances, responsibilities and procedures for the release of stored material before distribution (Standard Licence Condition T33b). This SOP includes the packaging requirements, shipping container requirements, labelling and security requirements (Standard Licence Conditions T105, T106, T107 and T108).

Centre staff are aware of the criteria for import and export under General Directions 0006, and know the procedure for applying for Special Directions for import or export. Examination of donor records showed that imports performed under General Directions 0006 met those criteria.

What the centre could do better.

Nothing noted

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

No embryos are kept or used at this centre and therefore no embryos are used in training.

What the centre could do better.

N/A

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 centre does well.

All three patient/partner records seen at the time of inspection were seen to be clear, legible and well organised. Each record reviewed was seen to include: patient/donor first name, surname, date of birth, age, sex, details of how the patient/donor had been identified, the treatment provided, a medical history, welfare of the child assessment, relevant documented consents, clinical and laboratory data and the results of tests carried out (Standard Licence Condition T46).

There is an SOP for submitting data to the HFEA, which is signed by staff to confirm they have read and understood it (Standard Licence Condition T33b).

Treatment data has been submitted to the HFEA as required by General Directions 0005.

The centre has facilities for storing patient records required for full traceability for 30 years (Standard Licence Condition T48).

What the 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 centre does well.

The PR provided all information as required by the application process prior to inspection (Standard Licence Condition T4). All members of staff cooperated fully with the inspection team and all further information requested at the time of the inspection was provided in a timely manner. The PR has complied fully with the recommendations from previous inspections with no outstanding issues.

What the 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 centre does well.

Staff at the centre provided evidence to demonstrate that all information is kept confidential and only disclosed in circumstances permitted by law and that they have processes in place to ensure that access to a centre's health data and records is secure at all times and is only available to persons named on the centre's licence or authorised by the Person Responsible (Standard Licence Conditions T43 and T44).

Consent to disclosure of information held on the HFEA register for use in research is not relevant for the patients at this centre as the centre only offers partner and donor insemination and storage of sperm.

What the centre could do better.

Nothing noted

5. Changes/improvements since the previous inspection on 3 March 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Legal Parenthood (guidance note 6) Discussion with the PR during the inspection indicated that the complexities of the new HFEA parenthood provisions may not have been fully understood. A patient information sheet was provided that included details regarding parenthood, but it was non specific to the wide variation of patients treated at this centre and did not appear to provide an adequate level of information. T61. The centre does not have a standard operating procedure to guide staff to provide appropriate parenthood documentation and inform patients of their specific parenthood rights. T33(b).	The PR should review all processes and procedures related to legal parenthood at the centre to ensure they comply with the 2009 provisions. The PR and QM should develop an SOP that covers the requirements of HFEA Code of Practice guidance note 6. The PR should audit the parenthood provisions and provide this audit to the inspectorate. The audit should review the consents for legal parenthood taken from 6 April 2009 and assure themselves that valid consents have been appropriately informed and captured on the correct forms. This may involve a review of each treatment involving donated sperm since 6 April 2009. By 12 June 2010	PR has reviewed processes and procedures related to legal parenthood to ensure they comply with 2009 provisions. Patient information and SOP relating to legal parenthood have been developed and were seen to be satisfactory. The PR has audited the consents for legal parenthood taken since 6 April 2009, and was assured that appropriate consent has been captured on the correct forms. Evidence of this has been provided to the inspectorate. No further action required.
Validation of air quality (guidance note 15) Air quality results were observed during the inspection and were found to be compliant with the requirements of T20. However the process has not been validated and the PR could not provide justification for the annual testing interval. T72.	The PR should validate the centre's air quality monitoring process, including justification for the regularity of testing. By 12 June 2010	The PR provided this information prior the report of March 2010 being presented to the Executive Licensing Committee. No further action required.
Third Party Agreements (guidance note 24)	The PR should review all agreements that the centre	This issue was resolved prior to the report of March 2010

Three third party agreements sampled during the inspection were found not to contain the requirement of the third party to meet the relevant HFEA licence conditions and guidance as required by T116.	holds with third parties to ensure that they comply with the requirements of guidance note 24 and in particular licence condition T116. By 12 June 2010	being presented to the Executive Licensing Committee. No further action required.
Witnessing (guidance note 18) During the inspection the witnessing of an IUI cycle was observed and some issues identified. The witness record sheet does not include the time and date of some of the checks, neither is it stated in the witnessing SOP that the time and date should be recorded at each step (T71, G18.6 and G18.7). Laboratory staff confirmed that patient identity is checked at the start of the procedure. However the SOP does not specify that there should be a check against patient records and this witnessing step is signed by one staff member only. T71. Laboratory staff are currently not performing witnessing at the time of each tube to tube transfer (T71). If one sample is processed at a time it is possible that the centre could witness only the first and final steps of the procedure (G18.30). However, currently the final step is not being documented as witnessed. During observation in the laboratory, some witness	The PR should review all witnessing practice at the centre to ensure that staff are following the standard operating procedure, including the requirement to witness each step contemporaneously. The PR should review the witnessing sheets to ensure that each critical step in the process can be clearly documented. By 12 June 2010	This issue was resolved prior to the report of March 2010 being presented to the Executive Licensing Committee. No further action required.

checks were not recorded contemporaneously		

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions 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	PR Response	Executive Review
None			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

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

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre does not always perform their own welfare of the child assessments when a patient who has had treatment elsewhere attends for treatment at the centre if a welfare of the child assessment has been performed at the previous	The centre should perform their own welfare of the child assessments when a patient who has had treatment elsewhere attends for treatment at the centre, even though the welfare of the child assessment has been performed at the previous	This has been implemented. All staff are aware. This has been included in an updated version of our SOP AS-2-11 Welfare of the Child Assessment version 3.	The updated SOP was provided to the inspector. The inspector is satisfied that this issue has been resolved. No further action required.

treatment centre (Standard Licence Condition T56).	treatment centre. Immediately.		
Information on the website is not compliant with Chair's letter CH(11)02, as the data presented is more than three years old and it does not state that statistics have limitations as a basis for comparisons.	The PR should review the information on the website and update the information as required to ensure it is compliant with Chair's letter CH(11)02. By 31 May 2012.	We are currently updating our website and will aim to complete this by 31 May 2012	The inspector considers that this is an acceptable response. The website will be checked for compliance after 31 May 2012.
Information for donors does not include the importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made (Code of Practice 11.24k).	The donor information should be changed to include the importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made. Before sperm donors are recruited.	The donor information has been changed accordingly	The donor information was provided to the inspector. The inspector is satisfied that this issue has been resolved. No further action required.
The patient information for donor insemination contained information intended for donors.	The patient information should to be corrected to make it relevant for patients. Immediately.	The patient information has been corrected accordingly	The patient information was provided to the inspector. The inspector is satisfied that this issue has been resolved. No further action required.

The PR may accept consent to legal parenthood forms completed at other centres if the patient has had treatment at that other centre and then requests treatment at centre 0293. (Standard Licence Condition T64 and T65).	Where consent to legal parenthood is completed at another centre, the PR must ensure that prior to treatment being given, there is a mechanism in place to ensure that consent to legal parenthood by either party has not been varied or withdrawn. Immediately.	This has been implemented and has been included in an updated version of SOP AS-2-12 Legal Parenthood Patient Information	The updated SOP was provided to the inspector. The inspector is satisfied that this issue has been resolved. No further action required.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

1 June 2012

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

Minutes – Item 1

Centre 0293 – (Andrology Solutions) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Mark Bennett, Director of Finance & Facilities Paula Robinson, Head of Business Planning	Joanne McAlpine

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that this is a small centre providing intrauterine insemination (IUI) treatment with both partner and donor sperm and has been licensed by the HFEA since 2007.

2. The Panel noted that the centre carried out 14 donor insemination treatment cycles and 190 partner insemination treatment cycles during the period 1 February 2011 – 31 January 2012, resulting in 28 pregnancies.

3. The Panel noted that at the time of the inspection the Inspectorate identified five other areas practice that required improvement.

4. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that four of the recommendations have been implemented and has given a commitment to fully implement the review and update of information on the centre's website to ensure it is compliant with Chair's letter CH(11)02.

5. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions.

Decision

6. 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.

7. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

8. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

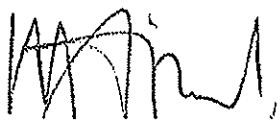
9. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

10. The Panel noted that the application does not involve the use of embryos for training purposes.

11. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that the Executive Licensing Panel will normally grant a

renewal licence for treatment/storage/non-medical fertility services licences for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

12. The Panel endorsed the recommendations made by the Inspectorate within the report. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed:  Date: 20/06/2012

Juliet Tizzard (Chair)