Inspection Report Renewal

Andrology Solutions
0293

Date of Inspection: 17 April 2008
Date of Licence Committee: 7 July 2008

CENTRE DETAILS

Centre Name	Andrology Solutions
Centre Number	0293
Licence Number	L-0293-1-a
Centre Address	55 Wimpole Street
Telephone Number	
Type of Inspection	Renewal
Person Responsible	Dr. Sheryl Homa
Nominal Licensee	N/A
Inspector(s)	Dr. Neelam Sood Chair, HFEA Executive Mr. Wil Lenton HFEA Executive Mr Richard Cullen HFEA Observer
Fee Paid – up-to-date	Yes
Licence expiry date	31st July 2008
NHS/Private/Both	Private

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About the Inspection:
This inspection visit was carried out on 17th of April and lasted for seven hours. The report covers the pre-inspection analysis, the visit and information received between 01/08/2007 and 03/03/2008.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

This report was written by the Head of Research Regulation who did not attend the inspection, but has compiled the report on the basis of the inspection notes made on the day by the inspectors who attended and that the recommendations are based on the evidence gathered by the inspectors

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre's premises comprises of:

- **Secured, ground-floor entrance hall to main reception**
- **Ground floor waiting room**
- **Stairs/lift access to lower ground (including wheelchair access)**
- **Office/counselling room**
- **Two semen production rooms**
- **One examination /insemination room.**

The centre has a treatment and storage licence, which includes the treatment of patients with partner or donor sperm via intra-uterine insemination and storage of partner or donor sperm.

The Person Responsible (PR) is an experienced reproductive scientists and has satisfactorily completed the PR Entry programme.

Activities of the Centre from 31/08/2007 to 31/12/2007

Licensed treatment cycles	37 cycles
Donor Insemination	None
Unlicensed treatments	None
Research	N/A
Storage	N/A

Summary for Licence Committee

The inspection team considered this to be a well organised centre with appropriately qualified, trained staff.

The Executive recommend the renewal of the centre's licence for 4 years.

Risk Assessment

The risk assessment is 16% (low risk)

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service	X		
3. Premises and Equipment	X		
4. Information	X		
5. Laboratory and clinical processes		X	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
S.7.8.5: The laboratory's documented procedures shall be established to ensure that processing of cells is performed using sterile conditions and under conditions of appropriate air quality.	**The PR took immediate action to monitor the air quality in the andrology laboratory and reports for settle plate cultures and air quality measurements for Class II flow cabinet and laboratory were sent within a week after the inspection. The PR also sent the centre's SOP for monitoring air quality. No further action is required.**	**N/A**
Not all the third party agreements have been finalised as required in standard licence condition A.5.1.	**The PR should ensure the agreements are followed up and finalised.**	**This will be monitored at the next inspection.**

Non-Compliance

Area for improvement	Action required	Time scale
The centre's witnessing procedures are potentially non compliant with the guidelines outlined in	**The PR should review all its witnessing processes and SOPs to assess compliance with HFEA**	**By 31 October 2008**

section G.13 of the Code of Practice (7th edition). For example the centre is not witnessing the removal of samples from cryostorage and evidence that all the processing and use of sperm had been witnessed was missing from laboratory work sheets and IUI patients' notes.	**guidelines. Any deviation from guidelines should be risk assessed.**	

Recommendations	Time scale
None	

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
None	

Additional licence conditions and actions taken by centre since last inspection

The centre was issued a one year licence with no additional conditions.

Report of Inspection findings

1.**Organisation**
Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
A documented organisational chart was provided pre-inspection. The organisational chart had a clear structure and operational procedures appropriate for the licenced activities. All staff interviewed were found to be aware of the reporting structure and of their individual responsibilities. The PR stated that all staff are appropriately qualified and experienced. Regular multi-disciplinary team meetings are held at the centre to discuss practice related issues. The minutes of the meetings are made available to all staff and examples of these were seen during the inspection. In the event of any emergency the centre staff have access to facilities located in the main hospital near by. The centre has a written contingency plan with another unit for emergency procedures. Regular audits of practice, results, patient feedback and of records are performed by centre staff. Incident reporting and complaints management protocols are in place and were discussed during the inspection. All documents supplied in support of the inspection showed evidence of version control and review. Information from the HFEA finance department showed that there were no issues with the centre over the payment of treatment fees.
Areas for improvement
Third party agreements were reviewed and the PR is still waiting for some third parties to respond to communications relating to the establishment of agreements. The inspection team recommends that agreements are finalised so as to meet standard licence condition A.5.1.
Areas for consideration

None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Business planning

Evaluation
Some improvements required.

2. Quality of service
Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
From the data submitted to the HFEA, during the period 31 August 2007 and 31 December 2007 the centre carried out 37 cycles of intrauterine insemination using partner sperm resulting in 5 pregnancies.
Areas of firm compliance
The centre has a quality manager in post and a quality manual which covers all the centres activities. All documentation is version controlled. The centre undertook a review of its quality management system in February 2008. The centre holds regular quality management meetings. Minutes of the meetings held since July 2007 up to the present day were seen during the inspection visit. There is a designated complaints officer who receives and assesses all complaints. Results, corrective and preventive actions arising from any complaints are discussed at the monthly quality management meetings. There is a staff suggestion scheme and any suggestions are discussed at the monthly quality meetings. A patient survey log book was seen during the inspection visit.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvements required

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
The premises and equipment were found to be fit for purposes. Access to the facilities where licensable activities take place is restricted to staff named on the centre's licence. The cryodrewars, used to store sperm, are fitted with low level nitrogen alarms, which are linked to an auto dialler. The laboratory is fitted with a low level oxygen monitor, which is linked to an audio and visual alarm system. The equipment in the laboratory has been validated. The service and maintenance logs for the equipment are in place and up to date. The equipment used for licensable activities is monitored regularly; for example the temperature of the incubators is recorded twice daily and the temperatures of the fridge and freezer are recorded once a day. The log used to record the monitoring of equipment was seen during the inspection visit. The media and consumables, used in the processing of samples for licensable activities, are traceable. The traceability log used for the media and consumables was seen on the day of the inspection. The centre has an SOP for monitoring air quality and has initiated the monitoring of the air quality in the laboratory where semen is processed. The centre has sent evidence of air quality monitoring to the HFEA; this indicated that laboratory air quality meets HFEA requirements.
Areas for improvement
None
Areas for consideration
The temperature in the laboratory was noted to be quite high due to the sun shining through a

glass skylight.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Counselling facilities

Evaluation
No improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy – **Not applicable**
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
The information provided to patients was considered appropriate. Patient records are stored in a locked filing cabinet within the main laboratory, which is secured via a key pad and is accessible only to staff named on the centre's licence. The centre has a SOP for the reporting of serious / adverse incidents to the HFEA. HFEA alerts are discussed at the monthly laboratory meeting. The majority of gametes are procured on site. Approximately 1 – 2% of samples are procured at home; a home procurement protocol has been developed.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Transportation, labelling of shipping container and recall

Evaluation
No improvements required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	1 + 0.05
NMC registered nurses	0
HPC registered scientists	1 full-time + 1 x 0.05 + 1 ad-hoc
Scientists working towards registration	1 full time + 1 ad hoc
Support staff (receptionists, record managers, quality and risk managers etc)	1 ad-hoc laboratory assistant + 1 x 0.05 support staff
Counsellors	1

Summary of laboratory audit / Audit of records
The centre has carried out an audit of its cryodewars – no anomalies were found. The audit of a sample of patients' records was found to be generally satisfactory, though in a couple of records the signature of the person who witnessed the laboratory procedure was missing.
Summary of spot check of stored material
Not carried out during this inspection visit.
Areas of firm compliance
The centre has adequate numbers of appropriately qualified and trained staff to deliver the service. The training records for staff were available on the day of the inspection visit. The training log / CPD for the andrologist was examined and found to be up to date. Staff are encouraged to attend conferences, seminars and relevant courses as part of their continuing professional development. The centre carries out an annual review of performance. The centre holds monthly minuted laboratory meetings (or more regularly if a change is implemented and information needs to be communicated to staff). . SOPs for all clinical and laboratory activities are clearly written and included within the quality manual.

The laboratory participates in the UK NEQAS scheme, an external quality assurance scheme. Andrology staff also undertake regular internal quality control exercises.

Areas for improvement
The removal of samples from cryostorage is not witnessed. The PR should consider amending the cryostorage sheet to include evidence that this procedure has been appropriately witnessed. The signature of the person witnessing the processing and use of sperm was missing from some of the laboratory worksheets within patient records audited during the inspection visit. The PR should ensure all witnessing is appropriately recorded.
Areas for consideration
None
Executive recommendations for Licence Committee
The Licence Committee is asked to note witnessing lapses found within patients records together with the observation that the removal of samples from the cryodrewars is not currently witnessed.
Areas not covered on this inspection
None

Evaluation
Some improvements required.

Report compiled by:

Name…Dr Chris O'Toole:

Designation……Head of Research Regulation……..

Date……10 June 2008……

Appendix A: Centre Staff interviewed

Appendix B: Licence history for previous 3 years

Current Licences

Licence	Status	Type	Active From	Expiry Date
L0293/1/a	Active	Treatment Only	01/08/2007	31/07/2008

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0293……

Name of PR……Dr Sheryl T Homa……..

Date of Inspection……17 April 2008……..

Date of Response……3 July 2008……

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name…….

Date……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Summary of Audit - Areas for Improvement p.17

"The removal of samples from cryostorage is not witnessed." This is incorrect as it implies that this is never done. In fact, all samples that are removed are witnessed with the exception of the one patient file audited during the inspection. There is an SOP in place for witnessing (AS-2-10 Witnessing Clinical and Laboratory Procedures see section 8.10 and 8.15 regarding removal of samples from cryostorage), and there has always been a clearly marked section for witnessing sample removal on the back of the lab sheet (see attached). I have now amended the witness sheet to include outcome of removed samples (see attached).

Perhaps the wording may be "**In one observed instance**, the removal of samples from cryostorage was not witnessed "

Non-Compliance (bottom of p.7)

It is also not true to say that "…the centre is not witnessing the removal of samples from cryostorage and evidence that all the processing and use of sperm had been witnessed was missing from laboratory work sheets and IUI patients' notes". Again this implies that this is never done. It is true to say :" evidence that all the processing and use of sperm had been witnessed was missing from **some** laboratory work sheets and IUI patients' notes". (See witness sheet attached)

2. Please state any actions you have taken or are planning to take following the inspection with time scales

Third Party Agreements p.7

Breach - Since inspection, we have received a further two signed Third Party Agreements from B Braun Medical Ltd and Resolution Microscope Service Ltd and we have a verbal agreement from the London Clinic and are waiting for them to put this in writing. We are in negotiations with the Princess Grace Hospital and 2 further hospitals where testicular sperm retrievals are performed. Currently we are also chasing up Marathon Laboratories and VWR International Ltd. All other Third Party Agreements are now in place

Witnessing p.7

Non-Compliance – An SOP for witnessing all procedures is in place and had been read and signed by all members of staff. This will be reviewed at the next staff meeting and all members of staff will re-read and sign the SOP. Laboratory sheets for sperm cryopreservation have been amended to include a column for witnessing outcome of sperm removal (see attached)

Laboratory Temperature p.13

We now have 2 quotes in for installing solar film over the skylight to significantly reduce the heat from the sun and plan to install it this month.

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

7 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Andrology Solutions (0293)
Licence renewal

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
Sally Cheshire, Lay Member	Claudia Lally, Committee Secretary
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Observing:
Neva Haites, Professor of Medical Genetics, University of Aberdeen	Bhavna Mehta, Inspector
	Angela Sutherland, Inspector
	Providing Legal Advice to the Committee:
	Graham Miles, Morgan Cole

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:

- papers for Licence Committee (29 pages)
- one tabled paper: response to the report by the Person Responsible (2 pages).

1. The papers for this item were presented by Debra Bloor, Head of Inspection. Dr Bloor informed the Committee that this centre is licensed to provide DI and IUI services and storage of gametes and provided 37 cycles of IUI in the time period from 5 July to 31 December 2007. Dr Bloor reported that the inspection had identified a small number of areas for improvement.

2. Dr Bloor informed the Committee that concerns about air quality monitoring had been raised on the day of the inspection but the Person Responsible took immediate action to monitor the air quality and submitted reports demonstrating compliance with HFEA requirements within a week of the inspection. Furthermore, the centre has developed an SOP for monitoring air quality which was also submitted.

3. Dr Bloor further informed the Committee that deficiencies in documentation of witnessing had been identified in a sample of records reviewed in the course of the inspection. Dr Bloor updated the Committee on action taken since the inspection by the Person Responsible. She reported that the Person Responsible has confirmed that an SOP for witnessing is in place and had been read and signed by all members of staff. The Person Responsible had reported that the SOP would be reviewed at the next staff meeting and all members of staff would re-read and sign the SOP. Furthermore, laboratory sheets for sperm cryopreservation had been amended to include a column for witnessing outcome of sperm removal.

4. Dr Bloor stated that at the time of the inspection a number of 3rd party agreements remained outstanding, however, the Person Responsible has reported progress in establishing a further 2 agreements in the time since the inspection and has committed himself to pursuing the outstanding agreements.

5. Dr Bloor reported that the Person Responsible is addressing the issue of the laboratory temperature.

6. Dr Bloor concluded with the observation that the inspection team considered this to be a well organised centre with appropriately qualified and trained staff. The Person Responsible had responded positively and proactively to the recommendations of the inspection and report and, accordingly, the Executive recommended the renewal of the centre's licence for 4 years.

The Committee's Decision

7. The Committee noted that the Person Responsible had requested that the report be changed to more precisely reflect the issues identified with the witnessing SOP and agreed that this would be done.

8. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

9. The Committee noted that the licence fee had been paid and agreed to renew the centre's licence for a period of 4 years with no additional conditions.

Signed…… … Date……..
Walter Merricks (Chair)