New Licence Application Inspection Report

Southampton Fertility Unit

Centre 0307

Date of Inspection: 23 September 2008

Date of Licence Committee: 15 October 2008

Centre Details

Person Responsible	Mr Nicholas Brook
Nominal Licensee	Dr Michael Marsh
Centre name	Southampton Fertility Unit
Centre number	0307
Centre address	Level G Princess Anne Hospital Coxford Road Southampton S016 5YA
Type of inspection	New Licence Application
Inspector(s)	Mrs Gill Walsh Dr Victoria Lamb Miss Allison Cummings
Fee paid	New Application fee paid.
Licence expiry date	N/A
NHS/ Private/ Both	NHS

Index

About the Inspection:

This inspection visit was carried out on 23 September 2008 and lasted for 7 ½ hours.

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 applied for and due for renewal, although other visits can be made in between.

The report summarises the findings of the licence application 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 application. The report is also available to patients and the public following the Licence Committee meeting.

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 the Person Responsible 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be addressed, 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

Southampton Fertility Unit is a small unit within The Princess Anne Hospital, a dedicated Women's Hospital and regional Neonatal Unit which is part of Southampton University Hospitals NHS Trust. The centre currently offers an andrology service and sub-fertility diagnosis and assisted conception treatment planning. Assisted conception treatment cycle monitoring is currently provided to patients as part of a satellite arrangement with two licensed treatment centres.

Mr Nicolas Brook is a Consultant Gynaecologist and Subspecialist in Reproductive Medicine and Surgery. Mr Brook has successfully completed the Person Responsible Entry Programme and has been discharging the duties of the Person Responsible (PR) under special directions since 7 June 2007.

This centre previously held an HFEA Licence which was suspended on 8 June 2007 by an HFEA Licence Committee as the Centre were unable to meet Human Fertilisation and Embryology (HFE) Act 1909, as amended by the HFE (Quality and Safety) Regulations 2007. The Centre does however, continue to store sperm and ovarian tissue for the preservation of fertility and donor sperm under special directions issued by the HFEA.

This Licence subsequently expired on 31 October 2007; no application to renew was made by the Centre at that time.

Since June 2007 a programme of building refurbishment, reallocation of space and capital investment in the equipment required for the provision of licensed treatment, has been undertaken by the Trust. There has also been a comprehensive review of the Centre's processes and an extensive audit of the gametes in store conducted.

Following this work, the Centre now believes their facilities and processes meet the required standards of the HFE Act and Code of Practice and have submitted an application for a treatment and storage licence.

Proposed Activities of the Centre

Insemination	✓
Treatment with donated gametes	✓
Storage of sperm	✓
Storage of eggs (ovarian tissue)	✓
Procurement and distribution of gametes	✓
Processing of gametes	✓
Non medical fertility services	✓

Summary for Licence Committee

The current team have conducted a thorough and comprehensive review of their practices and processes, as a result of which, significant change and improvement has been made in compliance with the HFE Act and Code of Practice.

In addition, the team have conducted a thorough and detailed audit of stored gametes.

In the opinion of the executive, robust systems are in place to manage the continued storage, release or disposal of gametes as required to ensure compliance with consents and the HFE Act.

The Centre has also undergone a programme of refurbishment of the laboratory and storage areas to ensure compliance with critical work space and environmental air quality requirements and also health and safety. Capital investment has been made in key areas to ensure equipment and facilities are appropriate for the treatment proposed.

The executive supports the centre's application and recommend that a Licence for treatment and storage as described be granted.

Evaluations from the inspection

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

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
Validation Validation of equipment and procedures is not yet being done. This may be in breach of licence condition A.11.11 and standards S.6.4.2 and S.7.8.3. The centre staff explained that they are waiting for documentation on this to become available from ACE/HFEA.	Validation of equipment and procedures should be undertaken.	By the next inspection.
Storage of gametes beyond consent. Despite robust processes now	The consent and storage issues surrounding these samples is to be	By December 1 2008

being in place, there are three samples being retained out of current consent, the circumstances of which was discussed with the Executive. (S.7.8.11)	resolved without delay, the result of which is to be communicated to the Executive.	
Policy for the positive identification of patients and partners. The centre does not currently have a documented overarching policy in place to verify the identity of patients or partners attending for treatment or donation. S.7.5.2. CH (99) 07	The Centre should ensure there is a documented procedure available to all staff to ensure that reasonable steps are consistently taken to verify the identity of patients, partners or those wishing to donate by asking for proof of identification. (G.3.4.1 G.4.6.2 G.6.1.1/2 G.13.7)	On or before December 1 2008
		.

Non-Compliance

Area for improvement	Action required	Time scale
Routine diagnostic and investigative procedures such as semen analysis are being performed in the centre's laboratory which is not CPA accredited. (S.7.8.2).	The PR should seek advice on the requirement for clinical pathology accreditation (CPA) for andrology diagnosis facilities.	If accreditation is considered to be required then a timeline for completion of accreditation should also be submitted to the HFEA.

Recommendations

Area for improvement	Action required	Time scale
Non documented high level contingency arrangements	The Centre should actively pursue a formalised written agreement between Southampton and Salisbury NHS Trust for contingency arrangements in the event of major disruption to service.	Six months.
Incident reporting documentation does not currently reflect the requirement to inform the HFEA of any significant incidence of Ovarian Hyper-stimulation Syndrome (OHSS).	The Centre should consider including the details of this requirement in their incident reporting policy specifically.	At the time of document review (due October 2008)
Validation of equipment and processes	It is recommended that the PR identifies the key pieces of equipment and processes which will need to be validated to ensure	

	compliance with Licence Conditions 11.11, 8.11 and 10.13 and Code of Practice Standards 7.8.3, S.6.4.2 and S.6.4.2. A programme of validation should be developed: the programme should take into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.	

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Payment of licence/treatment fees

Areas of firm compliance

Leadership and management

The Person Responsible (PR) has completed the HFEA PR entry programme and has satisfied the executive that he is fully conversant with the scope of his responsibilities as PR and his reporting obligations to the HFEA. (S.4.1.4 / 5 /7 / 8 / 9 / 11)

Current centre activities and proposed licensed treatment will be led by the Person Responsible, supported by the Nominal Licensee, who is fully engaged with the progress of the Centre. A small clinical and administrative team facilitate the day to day management of the Centre. (S.4.1.1 A.10.2)

Organisation

An up to date organisation chart was seen to be in place, demonstrating accountabilities and reporting relationships. (S.4.2.5 & S.4.2.6).

The centre appears well organised, with good communication within this small team at all levels. (S.4.1.1) Evidence of effective communication was seen in minutes of meetings. (S6.2.13)

Resource management

The PR stated that he felt confident the Centre had sufficient staff of the appropriate skill mix to fulfil the current activity but one andrologist post and additional administrative support is planned for the near future.

Risk management

The quality manager oversees the process for risk assessment at the Centre. The Executive saw a number of completed risk assessments for the laboratory and clinical areas and some evidence of positive action in changing and monitoring practice following risk assessment. Those conducting risk assessments stated that they had participated in Trust risk assessment

training. (S.7.8.10 S.9.4.3)

Clinical Governance
The Centre feeds into the Trust wide Clinical Governance agenda.

Incident management
The Centre has reviewed their incident management process. Incidents are managed in accordance with the Trust Incident Reporting policy and HFEA requirements. When asked, staff were aware of the incident reporting policy and of HFEA requirements, including time frames in which the HFEA must be notified of an incident. (S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1 S.7.7.8, S.9.4 and A.4

Alerts
The PR was able to describe an appropriate method of disseminating this information as required to the appropriate team members. It was stated that HFEA Alerts, amongst other matters was a regular agenda item at team meetings. Evidence to support this was seen in meeting minutes.

Complaints Management
There is a Trust wide complaints management policy in place. The Executive were informed that this is currently under review by the Trust. One individual has been nominated as the person to whom complaints should be directed within the Centre. The Centre complaints log was seen and illustrated the process by which complaints are managed. Information on how to complain or comment, including how to contact the HFEA directly, was seen to be clearly posted in patient areas. (S.4.2.9 S.9.5.4)

Contingency Arrangements
The Centre demonstrated that they have considered their best options in the event of disruption to service due to premises and equipment failure or catastrophic key staff absence. Some back- up equipment is available and some patients could be relocated within Princess Anne Hospital. Documented procedures to manage these eventualities were seen on inspection. (S.6.3.4 (b)) The Centre also has an informal agreement with licensed centre 0197 Salisbury Fertility Centre.

Members of the clinical and senior laboratory team participate in an on call rota to advise out of hours on urgent calls from patients, or respond to alarm activation or other laboratory alarms. The clinician on call can arrange for a patient to attend the Centre for assessment and scanning or to be admitted to the gynaecology unit which sits alongside the Centre.

The Centre is supported by the Trust emergency generator back up system and an uninterrupted power supply to key equipment (S,6,3,4 (b).

Payment of Licence Fee
The finance department of the HFEA confirm that this Centre has paid the licence application fee.

Areas for improvement

None at this time.
Areas for consideration
Executive recommendations for Licence Committee
None
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control

Areas of firm compliance

Quality Management System
There is a Quality Management System (QMS) in place and the Quality Manager has been working hard to develop the scope of the QMS to fully reflect all key elements of the Centre's service. (S.4.2.1, S.4.2.7, S.5.11 & S.6.1.1), evidence for which was seen on inspection.

Quality Policy
A quality policy has been developed and is in place and is available to all staff. (S.4.2.2/3 S.5.2.2 / 6)

Quality Manual
The Quality Manual was submitted for consideration with the Centre's licence application and was considered to be appropriate.

Quality Objectives and Plans
The quality objectives and plans for the Centre were seen to have been developed and were seen to be linked to the Centre's key performance indicators and the quality management review.

Quality Management Review
The Centre has not yet conducted a review, documentation indicating the scope and detail of a proposed review was seen to be compliant. (S.4.2.9)

Feedback
As part of their Quality Agenda, the Centre has a Patient Satisfaction Questionnaire which is available to all patients. The most recent analysis of which was seen on inspection. (S.9.2.1)

Document control
The Centre's policy documents were submitted to the HFEA with their Licence Application and many were available on inspection. The documents seen appeared appropriate, were version controlled and were within their specified review date of one year.

There was also seen to be a documented system in place to ensure any change in policy or

procedure is updated on the master 'K' drive and is communicated to relevant personnel and is confirmed and acted upon as required. (S.5.2.5).
Areas for improvement
None
Areas for consideration
It was noted that whilst the controlled documents presented were still within their review date, the Centre may should update certain documents to reflect, the correct name for Centre's Nominal Licensee and the HFEA 7th Code of Practice (doc 2.7) and may wish to include the HFEA's requirements for the reporting of OHSS (doc 6.6) in incident reporting documents.
Executive recommendations for Licence Committee
None
Evaluation
No improvement required.
Areas not covered on this inspection
All areas cover.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

General description of the premises and facilities.
The Centre is arranged over one floor (Level G) of the Princess Anne Hospital, a dedicated Women's Health and neonatal facility built in 1981, which is part of Southampton University Hospitals NHS Trust. Signage to the Centre is clear and access is via the hospital's main reception area, where patient's register at their first appointment, following which they will attend the Centre directly for their appointment and treatment. Should a patient's condition warrant ultrasound scanning out of hours, the Centre has access to the ultrasound scanning service of the Early Pregnancy service which is situated close by. The Centre's facilities are linked by a central corridor and comprise a waiting area, administrative office, treatment room and ultrasound room. There is also a men's room (with call bell), consulting rooms, laboratory and separate cryo storage room, office and staff washroom.
Areas of firm compliance
General suitability of premises In the opinion of the Executive, the general premises, clinical and laboratory facilities are suitable for the proposed licensed treatments. (S.6.3) Trust wide facilities contracts for waste management and cleaning are in place, evidence of which was seen. The Centre is covered by the Trust wide emergency power supply contingency plan. Key electrical equipment is connected to an uninterrupted power supply (UPS) S.6.3.1 / 2). The waiting area is simply but adequately furnished. Fresh drinking water is available form a dispenser. General patient information is displayed in this area. Information on how to make a comment or complaint, including to the HFEA directly was displayed. The PR stated that patient feedback indicated that the area could be improved and that the Centre are hoping to

refurbish this area. Posted along the central corridor are health and lifestyle posters, information on the counselling service and a visual display illustrating assisted conception techniques such as IVF, ICSI and information about current research. There is also a staff photo board displaying staff names and roles. The Centre offer healthy living, smoking cessation and weight management sessions which include the counsellors input.

Patient records are held in the Administrative office in locked cabinets. The room is also locked at the end of the working day and is otherwise constantly manned. The PR's office is within this area.

Clinical Facilities
All consultation, treatment and men's room facilities at the centre were seen to be considerate of patient and partner dignity and privacy whilst in consultation, examination or treatment at the centre. (S.6.3.4)

The treatment room is light and spacious; it appeared to be clean and well equipped, including a CODA tower which provides clean filtered air in this environment. Staff stated that the ultrasound scanner was under 18months old. Check lists for cleaning and decontamination of the ultrasound probe were noted, the sharps containers were signed and in date.

Staff also stated that an additional ultrasound machine was available for use by arrangement in the early pregnancy department if required. (S.6.3.3 / 4b)

A dedicated men's room is adequately furnished and has a 'call bell' in situ.

There is an emergency resuscitation trolley sited in the corridor which is shared by the adjoining Gynaecology Ward. The trolley was reported to be checked on alternate days (as determined after Trust risk assessment for this floor). This was confirmed by observation of the attached record sheet. (S.6.3.4 (b)).

Counselling Facilities
A dedicated counselling room is simply, but adequately furnished to give a less clinical feel. The room is quiet and affords privacy to the client and counsellor during sessions. (S.6.3.5)

Laboratory Facilities
There is an office currently used by laboratory staff in which some patient treatment and laboratory records are stored. All records stored in this area were seen to be stored securely within locked cabinets.

The laboratory has recently undergone a programme of refurbishment and upgrade of equipment. The laboratories appeared to be appropriately equipped for the type and number of treatments proposed.

The laboratory appeared to be clean and well maintained. (S.6.3.6) Access to all laboratory areas was seen to be strictly controlled and limited to licensed personnel only.

Air Quality
Assessment of background and critical work space air quality has been carried out both when

the lab is 'at rest' and operating. This is currently being conducted bi annually or more frequently if indicated. The results of tests showed that air quality was within acceptable range at the time of assessment. (S6.3.6 (b) Evidence of biological testing was also seen. (S.7.8.5)

Management of equipment and materials
Evidence of scheduled, preventative maintenance of laboratory and other equipment was provided in the course of the inspection. Equipment seen, including consumable items were seen to be 'CE' marked. (S.6.4.1/2).

Portable Appliance Test (PAT) was current on all equipment seen.

Storage Facilities for Gametes and Embryos
Following the recent refurbishment, there is now a separate, dedicated cryo store. The area was seen to be secure and access restricted by key pad lock to authorised persons only. (S.6.3.7 8) Staff stated that the key pad numbers to both the laboratory and the cryo store differ from the rest of the unit and are changed regularly.

Documented procedures to manage these eventualities were seen on inspection. (S.6.3.4 (b))

Staff Facilities
There is a staff washroom and secure locker storage for personal items within the Centre. Catering facilities and a staff rest area are provided in the staff dining room in the main hospital building. (S.6.3.9/ 10)

Storage of records
Medical records for patients currently attending the Centre are held in locked cabinets the main administration office. This room is always manned during Centre opening times and access to this room is controlled and locked out of hours. Archived notes of patients no longer in treatment and laboratory records are currently stored in locked cabinets in the laboratory office. Both areas were seen to be appropriately secure. (S.5.2.7 G.10.2.1).

Areas for improvement

Full validation of equipment has not yet begun. It is understood that guidelines for validation from the professional body ACE (Association of Clinical Embryologists) are to due for publication shortly and that the Centre is awaiting publication of these guidelines before beginning the process . (S.6.4.2 (a))

Areas for consideration

The Centre should consider validating the frequency of the air quality testing schedule to demonstrate that the air quality is maintained in the time between testing.

Executive recommendations for Licence Committee

Non at this time.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance

Information for Service Users

The Centre, with their application, submitted a copy of all patient information currently in use and that intended to support proposed licensed treatment.

Staff stated that, before any treatment is begun, the patient and partner receive both written and verbal information regarding all aspects of the proposed treatment, including consent, the effects and possible side effects of medication and treatment and a full description of any inherent risk involved. Patient information and treatment planning sessions are conducted in sessions with either the doctor directing their treatment or another appropriately experienced member of the Centre team, depending on their stage in treatment. Staff described that relevant written information would be printed contemporaneously from the Centre's 'K' drive of the computer network which is controlled, thus ensuring that only the most recent version of any document is handed to the patient. It was noted that patients whose treatment included ovarian stimulation are also given written information regarding ovarian hyper-stimulation syndrome (OHSS), how the patient may recognise symptoms and how to contact the Centre out of hours should they become unwell or have concerns. (S.7.4)

A checklist confirming the information given and the matters discussed is completed for each patient and is filed in the patient's medical record. An example of this was seen on inspection.

There is also general and some treatment specific information available to patients on the Princess Anne Hospital Trust website.

Consent

Staff asked, stated that the consent process is discussed with the patient from the initial consultation when treatment is offered and includes the giving and withdrawal of valid consent at any point during treatment or following storage of gametes. Valid consent may be sought by a member of the medical team prescribing treatment and may be discussed and confirmed by a suitably experienced member of the nursing team. The Senior nurse for the Centre confirmed that training is given in preparation for this and documented evidence recording supervision and assessment of competence in the task was seen on inspection. (S.7.4 S.7.5 S.7.8.4).

Welfare of the Child
The requirement to consider the welfare of any child born as a result of treatment or the effect of such a child's birth on existing children was discussed with both the counsellor and the senior nurse. Both parties were able to adequately describe the process by which an assessment should be undertaken and what further action to take in consideration of this should concern be raised. The Counsellor was able to describe two such examples and how they were managed, including the requirement for consent to disclosure when required. Comprehensive documentation to support this was seen. (S.7.6.4/5)

Access to Health Records
Health records are managed by the Centre's administrator and were seen to be securely stored. Access was seen to be restricted to appropriate personnel only. Documented procedures for the control of access to health records and requests for access to or copies of healthcare records from appropriate data subjects were seen to be appropriate. (S.7.2.2)

Provision of information to the HFEA Register
The Senior Nurse has been nominated as the individual responsible for submitting treatment and donor information to the HFEA.

Areas for improvement
None
Areas for consideration
Executive recommendations for Licence Committee
None at this time.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	2
Non NMC registered clinical staff	
HPC registered scientists	1
Scientists working towards registration	1
Support staff	2
Counsellors	1

Summary of laboratory audit
A comprehensive historical audit of material stored at the Centre has been submitted to the HFEA for consideration prior to the inspection. As a result of the historical audit of stored samples, patient contact and consent, patient records were now seen to be systematically stored in consent expiry order. A robust policy for managing this process was seen to be in place. (S.7.8.12) Staff stated that as part of that process, currently three samples remain outstanding whereby the samples are being stored without written consent. The circumstances surrounding these samples was described and as a result the inspectorate felt confident would be resolved within a short space of time dependant on the awaited response from the patients and that with the system now in place the likelihood of this recurring was minimal. This will however be a focus for any future inspection. (S.7.8.12)
Summary of spot check of stored material
The Scientific Inspector conducted a spot check of four (4) samples of cryopreserved material from patient records to sample and stored sample to patient records and no discrepancies were found. All consents were seen to be present and compatible with the treatment/service

provided.

Areas of firm compliance

Staff training and competence

The job description and training record of a randomly selected member of the nursing team was seen on inspection. Recent training included all Trust mandatory training in fire, manual handling, resuscitation, COSHH and also risk assessment, incident reporting and complaints, infection control, child protection and data protection. The senior nurse has also undertaken formal ultrasound scan training and hopes to extend this to other members of the nursing team over the next year. A qualified ultrasonographer supervises practice.

A competency framework and supervision log for a number of clinical practices was seen. (S.6.2.5 /7/8/9) Staff asked stated that they were also subject to new starter then annual appraisal. (S6.2.10).

The Laboratory Manager is Health Professions Council (HPC) registered and stated that she will be taking the Royal College of Pathologists Part 1 examination for Clinical Embryologists in July 2009.

The second member of the lab team is currently in training, she has a PhD and is an associate member of the Association of Clinical Embryologists (ACE).

Evidence of local training and competency assessment in semen analysis was also seen. Formal training with the Association of Biomedical Andrologists (ABA) is planned for the coming year, the Centre are awaiting confirmation of a new date as a result of a change made by the ABA. Verbal confirmation of induction and mandatory training was given. (S.7.7.2)

Evidence of participation in the National External Quality Assessment Service (NEQAS) for laboratory medicine was also seen, the results of which were within acceptable range.

Screening of Donors

The Centre is not currently recruiting donors but intends to re-establish the sperm donor programme in the coming months when licensed treatment is established. A protocols for the selection and screening of potential donors was seen. Staff stated that these protocols would be actively reviewed prior to donor recruitment commencing. (S.7.6.6 /7/8 S.7.8.12)

Procurement, distribution and receipt of gametes

The Scientific Inspector was able to discuss and review documentation regarding:

- the transfer or receipt of gametes to or from another centre . (S.7.7.1 – 15) (checked against audit tool).
- the use of donor gametes and the 10 family limit (S.7.7.4 / 5) (S.7.8.12)
- the receipt and verification of semen samples produced away from the Centre. (S.7.7.9 10)

All documentation was considered to be compliant.

Traceability
Evidence was seen on inspection that there is a documented procedure in place and that practice assures the traceability of gametes and of the equipment and consumables which may affect the quality of gametes. (S7.3.1/2)

Coding / Identification of Samples
In some circumstances the centre processes sperm produced by male patients at home. In these circumstances, the centre asks the male patient to sign to confirm that the sample is theirs *(G.2.3.1*). Evidence of this was seen in patient records during the inspection. The process for identifying and labeling samples was also seen to be appropriate.

Witnessing
The Scientific inspector was to discuss and review witnessing processes and documentation which appear to be compliant with HFEA Code of Practice Guidance (G.13) It was agreed that a small modification to the Centre's witnessing form was required for greater clarity.

Counselling Practice
The Counsellor has been working with the Centre for approximately four years and is independent of the Trust, being contracted to provide 15 hours per week. She is professionally qualified in psychodynamic counselling and has a regular professional supervision session each month. In discussion the Counsellor was able to describe good integration with the team and involvement with patient information and care initiatives set up by the Centre such as lifestyle advice sessions regarding health and conception and 1:1 counselling sessions with patients affected by polycystic ovary syndrome and weight management issues. Patients may contact the counsellor directly via a dedicated phone line if they wish. There was seen to be a comprehensive programme of support and implications counselling being offered. There is an onward referral system should more complex or extended therapeutic counselling be required.

The Counsellor reported that she had over recent months had the opportunity to revise the counselling protocols for the Centre and written patient information as part of her own professional development and also takes part in mandatory training as provided by the Trust. The Counsellor was also able to describe full involvement in team meetings and in the evaluation of patient feedback to the Centre. The Counsellor also described her aspiration to gain greater patient feedback on the counselling service specifically. An audit of counselling services uptake was seen.

As an independent practitioner, the Counsellor is part of a wider organisation which provides contracted and self funded counselling services to a number of assisted conception units in the region, with whom there is a reciprocal cover arrangement in the case of a significant disruption to the service. All counselling records are securely held at the Centre and are supervised by the Counsellor, access to which was seen to be securely controlled. (S.6.3.5 S.7.5.4 S.7.6.3.2 G.7)

Areas for improvement

Selection and Validation of Laboratory Procedures
A validation SOP and template for equipment validation were seen to be in place, evidence that validation of equipment and key processes has taken place was not provided. 7.8.3, S.6.4.2 and S.6.4.2.

Storage out of consent. Three patient samples are currently being stored out of consent. (S.7.8.11)
Areas for consideration
Executive recommendations for Licence Committee
None
Evaluation
Some improvement required.
Areas not covered on this inspection
3 Embryo transfer – not conducted at this Centre.

Report compiled by:

Name: Gill Walsh

Designation: Inspector

Date: 2nd October 2008

Appendix A: Centre staff interviewed

The Person Responsible, The Nominal Licensee Six members of the Centre Team.

Appendix B: Licence history for previous 3 years

N/A – new application

Appendix C: Response of Person Responsible to the inspection report

Centre
Number……0307……

Name of PR…Mr Nicholas Brook

Date of Inspection…23.9.08

Date of Response…14.10.08

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

Signed……NB (Hard copy to follow)

Name…….

Date……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

No, the report is a true reflection of the Unit and the processes and procedures now in place.

However we would like to clarify a couple of points

(1) The query raised in the report regarding the higher incidence of OHSS in stimulated cycles has been amended in both DI and IUI information sheets but please clarify where in the patient information it inferred that OHSS was increased in donor sperm cycles. If you could expand on this we will make the appropriate changes. *This was incorrect as the sheet actually referred to the possible increased incidence of pre-eclampsia in donor sperm pregnancies, not OHSS. This has been corrected.*

(2) Is the ? (question mark) before "considered" in the paragraph on the quality manual (page 12) a query to do with our quality manual or a typing error? *Typographical error- this has been corrected.*

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

We are in discussion with the main hospital laboratory to clarify the requirements for CPA for our diagnostic andrology services. I will liase with the HFEA once a clear pathway and time-line has been established.

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

Attached is updated form for IUI prep with clearer witnessing format to denote 2 witnesses necessary and time of IUI

Also has new footer to include HFEA centre number. Code of Practice version, and Nominal Licensee details. This will be included on all forms at their review date.

Further updates:
1) All 3 expired consents are now finalised - 2 discarded due to loss of contact, and 1 appropriately extended consent.

2) Validation of processes has now begun, although awaiting ACE input for clarification.

In addition please find attached new versions of the following:-

Doc 105 Semen analysis results with IUI/freezing
Doc 151 worksheet IUI Checklist
Doc 612 SOP IUI Nursing appointment
Doc 702 Information sheets Artificial insemination by donor,
Doc 705 Information sheets intrauterine insemination,
Doc 834 Patient letter for IUI
Doc 836 Policy for ID check of all patients

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

15 October 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Southampton Fertility Unit (0307)
Initial licence application

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Chris O'Toole, Head of Research Regulation
Emily Jackson, Lay Member	Claudia Lally, Committee Secretary
Richard Harries, Lay Member	
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Providing Legal Advice to the Committee: Mary Timms, Field Fisher Waterhouse Solicitors

Conflicts 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 (63 tabled pages)

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre was previously licensed under the name "Princess Anne Fertility Unit". In June 2007, a Licence Committee considered a renewal inspection report of the centre which reported a number of breaches of the Human Fertilisation and Embryology Act 1990 and the Code of Practice. The Committee decided to temporarily suspend the licence for the reasons that these breaches represented failures to secure that proper equipment is used and that suitable practices are in use in the course of the centre's activities. Mrs Walsh explained that the Committee had also issued Special Directions to allow for the continued storage of samples until such time as a final determination is made on the licence renewal. Subsequently, the centre's licence was allowed to lapse as the centre was still unable to fully meet the requirements of the Human Fertilisation and Embryology Act 1990 and the Code of Practice. Special Directions have been in place since that time.

2. Mrs Walsh informed the Committee that an application has now been received from the centre for a new licence. She explained that the centre staff have been working hard to ensure that the historical problems identified in the renewal report of 2007, along with issues that have been identified since that time which relate to damaged labelling on some of the samples in long-term storage, have all been resolved.

3. Mrs Walsh reported that an inspection visit took place to the centre on 23 September 2008. The inspection found that following refurbishment, considerable positive change had been brought about in both the premises and in the equipment available for use in the treatment of patients. The current team have conducted a thorough and comprehensive review of their practices and processes. As a result of this review, significant change and improvement has been made in compliance with the HFEA Act and Code of Practice. However, some small areas for further improvement were identified at the inspection, under the headings “Premises and Equipment” and “Laboratory and Clinical Processes”.

4. Mrs Walsh informed the Committee that a response to the report has been received from the proposed Person Responsible: Mr Brook. The response records Mr Brook’s commitment to addressing all the areas for improvement identified in the report. Mrs Walsh recommended that the Committee grants the centre a three year licence.

The Committee’s Decision

5. The Committee noted the application from Mr Brook to be Person Responsible for the centre. They noted that Mr Brook is a Consultant Gynaecologist and Subspecialist in Reproductive Medicine and Surgery. The Committee also noted that Mr Brook has satisfactorily completed the Person Responsible Entry Programme (PREP) assessment and has been discharging the duties of the Person Responsible under Special Directions since 7 June 2007. The Committee agreed that they were satisfied as to the character, qualifications and experience of Mr Brook, and furthermore that they were satisfied that Mr Brook will discharge the duties required of him under Section 17 of the Act.

6. The Committee also took into account the fact that Mr Brook has responded to the recommendations made by the inspection team and had taken action to implement those recommendations.

7. The Committee noted that Mr Michael Marsh has applied to be Nominal Licensee for the centre. They noted that Mr Marsh is a Consultant Paediatrician and Divisional Director for Women’s Services. The Committee also noted that Mr Marsh is very engaged with the running of the centre. They agreed that they were satisfied that Mr Marsh is a suitable person to hold a licence.

8. The Committee noted that the centre was to be based in new, purpose built premises. On the basis of the inspection report and the Person Responsible's response, the Committee agreed that they were satisfied as to the suitability of the premises. The Committee noted that a signed application has been received and a fee has been paid for the new licence.

9. Taking into account the recent history of the centre, and the basis of Mrs Walsh's recommendation, the Committee decided to grant the centre a three year licence, though they requested that an inspection visit to the centre takes place after the first 12 months, after the centre's new practices have had a chance to become established.

10. The Committee noted that the centre's Special Directions with respect to the stored sperm will expire on 31 October 2008.

Signed……. … Date……..
Anna Carragher (Chair)