Interim Inspection Report

Southampton Fertility Unit

Centre 0307

Date of Inspection: 23 July 2009

Date of Licence Committee: 23 October 2009

Centre Details

Person Responsible	Mr Nicholas Brook
Nominal Licensee	Mr Michael Marsh
Centre name	Southampton Fertility Unit
Centre number	0307
Centre address	Level G Princess Anne Hospital Coxford Road Southampton SO16 5YA
Inspection Date	23 July 2009
Type of inspection	Interim
Inspector(s)	Mrs Gillian Walsh Dr Andrew Leonard
Licence	L0307-1-a
Licence expiry date	30/11/11
NHS/ Private/ Both	Both
Fees paid to date?	No fees currently due.

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About the Inspection:

This inspection visit was carried out on 23 July 2009.

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.

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.

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

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 has been licensed by the HFEA since December 2008 to conduct partner and donor intra uterine insemination (IUI) and for the storage of gametes. The centre also offers an andrology service, the investigation and diagnosis of sub-fertility and assisted conception treatment planning.

The University of Southampton has recently appointed a Professor to the Chair of Reproductive Medicine who will be joining the team in October 2009. In conjunction with the team, he will be instrumental in the proposed further development of assisted reproductive therapies at the centre which is currently in the planning phase with Southampton University Hospitals NHS Trust. It is proposed that over the next two to three years the footprint of the existing centre will be extended into adjoining accommodation, offering increased treatment capacity and to expand the range of treatment and facilities available to full IVF/ICSI.

Person Responsible for the centre is Mr Nicholas Brook, Consultant Gynaecologist and Subspecialist in Reproductive Medicine and Surgery with Southampton University Hospitals NHS Trust. Mr Brook has successfully completed the Person Responsible Entry Programme (PREP) and has been discharging the duties of the Person Responsible (PR) under special directions (for the storage of gametes) since 7 June 2007 for Centre 0121 which closed.

The centre is open for clinical consultation and treatment Monday to Friday 8am to 5pm and occasionally open on Saturday for surgical sperm retrieval procedures. The centre has a busy outpatient diagnostic and treatment monitoring service which includes ultrasound scanning. The ability to provide greater numbers of IUI treatments has been restricted due to PCT funding restrictions.

Activities of the Centre[1] for the time period from December 2008 to June 2009

Intra uterine insemination (IUI) (partner and donor)	39
Storage gametes	yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

Summary for Licence Committee

In considering overall compliance, the executive considers that it has 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 has discharged his duties under Section 17 of the HFE Act. and that those acting under the supervision of the PR are suitably trained and qualified for their designated roles. Patients report satisfaction with the treatment that they receive
- the executive believes that the premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- the centre has been proactive in the development and implementation of a quality management system which in the opinion of the executive is of a high standard
- the executive is satisfied that, the centre demonstrates suitable practices in respect of air quality, laboratory, clinical and administrative procedures conducted in relation to licensed treatments.
- the centre has submitted comprehensive documentation of a high standard in preparation for their inspection.

The executive considers that, overall there is sufficient information available to recommend the continuation of this centre's licence without additional condition.

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
Clinical Pathology Association (CPA) Accreditation for the Andrology Laboratory 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 Centre were able to demonstrate active planning toward gaining CPA for their laboratories and a lead for this project has been identified by the centre. The centre have agreed a target of full compliance with CPA guidelines by March 2011 and to be assessed for CPA accreditation by July 2011. The centre are to continue in pursuit of CPA accreditation in accordance with the action plan presented. Any deviation or barriers to the anticipated compliance and assessment time scales should be communicated to the HFEA by the centre as soon as they are known.	To be monitored in the course of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale

Recommendations

Area for improvement	Action required	Time scale

Changes/ improvements since last inspection

Recommendations	Action Taken
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.	Key equipment and processes have been identified including equipment and materials used in all semen analysis and processing. External validation has been commissioned where the centre feel they cannot validate in house, evidence for all of which was seen on inspection. Clinical processes and air quality monitoring has been validated, documented evidence of which was also seen on inspection as was seen to be

	appropriate and in good order.
Storage of gametes beyond consent. Despite robust processes now 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)	This issues was resolved following the last inspection and was communicated to the HFEA at that time. This was confirmed on inspection in interview, observation of records and spot audit on inspection. No further action required.
Policy for the positive identification of patients, partners and donors. 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	This was resolved immediately following the last inspection and was communicated to the HFEA at that time. Observation of practice and documentation on inspection confirmed appropriate changes to practice and in the centre's standard operating procedure (SOP) where by all patients and donors attending the centre since that point have confirmed photographic identification on file.
Clinical Pathology Association (CPA) Accreditation for Andrology Laboratory 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 centre were seen to be actively progressing toward CPA accreditation for andrology and have extensively discussed the requirements with CPA Ltd. toward compliance. The centre has also sought advice and benchmarking with the only purely IVF / Andrology laboratories to gain CPA accreditation thus far nationally. A comprehensive action plan was seen with goals set at compliance with all CPA guidelines by March 2011 with and inspection by CPA before July 2011. A designated lead for this process has been nominated by the centre.
High level contingency arrangements Non documented high level contingency arrangements	A high level agreement for the continuation of patient treatment services was agreed and signed by the centre and a neighbouring licensed centre in January 2009, evidence for which was seen on inspection.
Inclusion of Ovarian Hyper-stimulation Syndrome in HFEA Incident Reporting Incident reporting documentation does not currently reflect the requirement to inform the HFEA of any significant incidence of Ovarian Hyper-stimulation	The centre's HFEA Incident Reporting SOP has been amended to include the reporting of incidences of the OHSS where required. This SOP was seen on inspection.

Syndrome (OHSS).	

Additional licence conditions and actions taken by centre since last inspection

No additional licence conditions apply

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
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The centre's activities are lead by the PR, Mr Nicholas Brook, who is supported by a small, highly experienced clinical and administrative team. The PR is also supported by the Nominal Licensee who was also present on inspection and takes an active part in the centre's activities and meets with the centre's management team monthly. In the opinion of the executive, evidence drawn from the inspection demonstrates that the PR provides the required leadership and management skills to fulfil his responsibilities. During the inspection the centre appeared to be operationally well organised. All pre-inspection material was submitted to the HFEA complete and on time. All members of staff requested were present for the inspection and provided all the information, written and verbal,

as requested.

An organisational chart was seen to be in place which clearly demonstrated current responsibility and reporting lines. Evidence of regular management communication and review of centre activities, including material and human resources, was seen in the minutes of management group meetings.

The centre participates in the Trust wide clinical governance agenda and was able to demonstrate effective risk awareness on discussion with staff and in reviewing risk assessments undertaken since the last inspection. Key areas of the centre's activities were seen to have been comprehensively risk assessed since last inspection. Risk assessments undertaken include those for procedures undertaken, equipment in use and changes to premises. The centre's SOP for risk management was seen as was evidence of a regular three monthly health and safety assessment being undertaken and a monthly fire safety assessment having been undertaken by a nominated 'Fire Group' leader. The results of a number of internally conducted audit were seen.

The centre manages incidents and complaints in accordance with the Trust polices and HFEA requirement. Both the centre's incident and complaints logs were viewed. The centre's incident and complaints standard operating procedures (SOP) were seen to be in place. Information regarding how and to whom a complaint should be made was available in patient areas. When asked staff were aware of the HFEA Alert system but had been unaffected in their practice by resent Alerts.

The PR stated that contingency measures are in place to manage the following eventualities and disruption to service:

- Power 'outage' – the centre is part of the Trust emergency back up generator network
- Significant absence of the PR – there is a Nominal Licensee in place and appropriate clinical cover available
- Significant disruption to clinical service on site – an agreed, signed contingency arrangement is now in place with another local HFEA Licensed centre for patient to continue their treatment there. (Seen)
- Patients requiring admission to hospital under emergency conditions are managed in the gynaecology ward, located within the campus of Princess Anne Hospital. (SOP seen). Instructions for emergency arrangements (including out of hours) are contained in the patient information leaflets.
- Equipment for use in the resuscitation of a patient who may collapse is available for use in the centre and was seen to be checked daily.
- The laboratory staff participate in an 'on call' rota in the event of an alarm being activated in the cro-store.

Details of all third party agreements in place were seen on inspection.

The finance department of the HFEA report that the centre currently has no fees due.

Areas for improvement

None

Areas for consideration
None
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
- Live birth rates

Live birth rates[1]
The centre has conducted only a relatively small number of licensed procedures since gaining their licence in December 2009 and do not have a full year's treatment data on which to conduct an audit of results against national averages.
Areas of firm compliance
Since last inspection, the PR and staff within the unit have demonstrated commitment to the further development of the Quality Management System (QMS). The Laboratory Manager who also has the role of Quality Manager leads the development of the QMS and oversees the activities of respective team members with designated quality management responsibilities within that framework. The centre's commitment to quality is outlined in their policy within the quality manual and incorporates all elements required by the 7th Code of Practice. In compliance with HFEA Standards, the quality manual clearly outlines: (a) a description of the centre, including its legal identity, and the scope of the services provided, (b) a quality policy (c) an organisational chart and a definition of the centre's place in any parent organisation, (d) an outline of the processes and documentation established for the quality management system. Quality objectives and key performance indicators (KPI) have been agreed and established for key activities at the centre including clinical and laboratory performance, complaints, incidents, patient satisfaction, staff feedback, attendance and leave monitoring. These KPIs are monitored monthly and reviewed routinely bi annually unless monitoring results indicate otherwise, evidence of which was on inspection. The centre has also established an annual audit schedule which includes audit of patient notes, risk assessments, staff training, staff competencies, witnessing procedures, 3rd party agreements, counselling, consent (to cryopreservation and treatment) and staff appraisal. Evidence of audits conducted most recently for cryo-preserved gametes, administrative

process, IUI and DIUI and IUI SOP to practice audits were seen on inspection. An analysis of the findings, together with any action plan / evaluation of the actions for each audit was provided for the inspection team to review.

Patients, their partners and donors attending the centre are invited to complete a 'patient questionnaire', the results of which are collated and discussed at the monthly KPI meeting and at the next available clinical meeting if required.

Staff asked stated that all staff members as available attend the weekly team meeting and are encouraged to comment and contribute. The staff also stated that they have a system where by any member of the team can 'table' a topic for discussion at this meeting via a communal 'whiteboard'. Sample minutes for this and other centre meetings were seen on inspection and would appear to support this.

The centre has a document control policy in place which was seen to be compliant with HFEA requirements. Staff asked were able to describe their practice in line with the centre's policy. Controlled documents received prior to and during the course of inspection were seen to be within review date and compliant with HFEA Standards being uniquely identified, version and date controlled, author identified and authorised for issue.

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

3. Premises and Equipment

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

Brief description of premises
The Centre is arranged over one floor (Level G) of the Princess Anne Hospital and may be considered suitable for disabled access. Signage to the Centre is clear and access is via the hospital's main reception area, where patients register at their first appointment, following which they will attend the Centre directly for their appointment and treatment. 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, counselling room, laboratory and separate cryo- storage room, offices and staff washroom.
Areas of firm compliance
The premises and facilities available appear to be suitable for the activities for which the centre is licensed. The patient waiting area is shared by all service users attending the centre. The area was basic but comfortable furnished. Information for service users regarding treatment options, support groups, what to do in the event of a complaint, lifestyle choices for the improvement of health and wellbeing and also a photographic 'who's who' of centre staff were displayed. The centre's HFEA licence was also seen to be displayed and information about the counselling service. The clinical facilities appeared to provide for the privacy, dignity and comfort of (i) those seeking treatment and (ii) those undergoing examination and treatment and (iii) providing semen samples for therapeutic use. The treatment room is light and spacious; it appeared to be clean and well equipped, and included a CODA tower which provides clean filtered air in this environment. Check lists for cleaning and decontamination of the ultrasound probe and other equipment was noted, the

sharps containers were signed and in date.

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

The laboratory currently contains two Class II flow cabinets and appeared to be appropriately equipped for the type and number of treatments proposed. The laboratory appeared to be clean and well maintained. Access to all laboratory
areas was seen to be strictly controlled and limited to licensed personnel only.

Assessment of background and critical work space air quality has been carried out both when the lab is 'at rest' and operating. The air testing protocol has been effectively validated and the frequency for which justified by the centre. Air quality monitoring is currently being conducted bi annually (particle) and quarterly for microbiology (settle plates) or more frequently if indicated. Detailed historical results for air quality testing were available on inspection and were seen to be compliant with HFEA requirements. The most recent air quality monitoring results for June / July 2009 for the laboratory workstation (cabinet running), laboratory background air and in the treatment room (CODA tower in situ) were all seen to be compliant with HFEA air quality requirements.

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.

There is a separate, dedicated cryo store. The area was seen to be secure and access restricted by key pad lock to authorised persons only. 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. All dewars were seen to be connected to a now N_2 alarm system. A low 0_2 alarm system was also seen to be in place which is tested weekly, evidence of which was seen on inspection. Documented procedures to manage any untoward events in this area were seen on inspection.

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.

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. No patient records are stored off site.

Areas for improvement

None

Areas for consideration

None
Executive recommendations for Licence Committee
None
Evaluation
No 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
Prior to inspection the centre submitted a list of all patient information currently in use, examples of which were also available on inspection. On examination of the written patient information in use and in discussion with centre staff, the executive is satisfied that the centre provided appropriate oral and written information to prospective patients, donors and those wishing to store gametes which explains the medical, scientific, legal and psychosocial implications of their actions. Those affected are given sufficient time to reflect on the information they have received and are given the opportunity to ask further questions or seek clarification from appropriate staff before consent is sought. 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 is printed contemporaneously from the Centre's 'information hub' of their computer network which is controlled, thus ensuring that only the most recent version of any document is handed to the patient. 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 website. The centre has a documented procedure to ensure that only personnel authorised by the centre may seek valid consent from individuals considering examination, treatment, donation or storage of gametes which also ensures reasonable steps are taken to verify the identity of the person from whom consent is sought which is compliant with current professional and HFEA guidelines. Confirmation of identity by photographic record in the healthcare records of individuals giving consent was seen in a random selection of records viewed on inspection. Staff asked, stated that the consent process is discussed with the patient at their initial consultation when treatment is offered and includes the giving and withdrawal of valid consent during treatment, donation or storage of gametes. Special consideration is given to individuals considering consent to parenthood were donor gametes are used in treatment. Valid consent may be sought by a member of the medical team prescribing treatment and may be discussed and confirmed by a suitably authorised member of the 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. An audit of patient / donor consents to treatment and / or storage was seen to be included in the audit schedule.

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 senior nurse who was able to describe the process by which an assessment should be undertaken and what further action to take in consideration of this should concern be raised. Comprehensive documentation to support this was seen. A documented SOP to support this was seen to be compliant with HFEA requirements.

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 compliant with HFEA requirements.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
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
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	1.5
NMC registered nurses	2
Non NMC registered clinical staff	0
HPC registered scientists	1
Scientists working towards registration	1
Laboratory support staff	1
Support staff (administrators, record managers, quality and risk managers etc)	2
Counsellors	1

Summary of laboratory audit
Gametes for cryo – preserved for the preservation of fertility – conducted June 2009. The centre holds seven large tanks and one small vessel in which a total of 775 samples for 387 patients. The audit comprised a full count of straws in the tanks which were cross checked against patient notes and also names and straw numbers drawn from the database compiled following the 2008 audit (on transfer to licensed centre 0307). Of the 775 samples overall, 17 discrepancies were identified. On analysis the centre has determined that of these discrepancies over half were due to a miscount of the samples during the 2008 audit of samples as the accuracy of the database with which to cross reference samples would not be guaranteed. All discrepancies have been aligned with the current database and the centre state that they are now confident of it's accuracy against samples help is store. Samples banked since December 2008 have been stored separately form 'inherited' samples using different storage methods with improved labelling and stability measures. No discrepancies were found on audit of these two tanks. **Cryo – preserved donor sperm - conducted April 2009** A full audit three donor sperm only dewars (H, D & B) was conducted and did not identify any discrepancies.

Cryo – preserved donor sperm – conducted March 2009
A full audit on this dewar was conducted and identified four discrepancies. The donor files were updated, there was no potential loss to patients.

Cryo – preserved ovarian tissue – conducted June 2009
A full audit of this dewar was conducted, no discrepancies against patient records and the centre database were found.

Audit if IUI preparation witnessing conducted – June 2009
An audit of 10 randomly selected files was conducted. Each file was checked for confirmation of appropriate witnessing steps at eight key points in the IUI process. No discrepancies or omissions were found.

Summary of spot check of stored material

A spot check was not conducted on this occasion due to the recent completion of dewar audit.

Areas of firm compliance

On review of information provided by the centre, the executive concludes that the centre staff are suitably trained and qualified for their designated roles in accordance with current professional and HFEA guidelines.

The job description and training records for members of the nursing and laboratory team were 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. Training also included child protection, data protection and evidence of role specific continuous professional development.

It was noted that a number of staff members (including medical staff) had attended inter centre benchmarking visits within the last six months. A report of each visit has been written by each team member and presented at the weekly team meeting, evidence of this was seen on inspection.

Clinical and laboratory staff asked were able to describe the centre's process for competency assessment and could demonstrate that they had a comprehensive competency framework corresponding with there role. Staff stated that each competency level was 'signed off' by their assessor once confidence and competence in the task was demonstrated and agreed by both parties. The Quality Manager stated that for those that require competency assessment at a more senior level or for whom there is no suitable assessor on site, an external assessor is used. Evidence for this was seen in the Laboratory Manager's own competency file.

The Quality Manager stated that the performance of all staff is reviewed at least annually by their line manager and that staff are encouraged to feedback on their performance and training and how they believe their performance may be enhanced. Staff asked supported this in practice stating that they had participated in new starter Trust and local departmental induction and regular, collaborative appraisal.

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.

The centre has a documented validation process for the validation of clinical and laboratory procedures which was seen to be compliant with HFEA requirements. Evidence of clinical and laboratory validation was also seen on inspection and was also considered compliant with HFEA requirements.
Areas for improvement
Routine diagnostic and investigative procedures such as semen analysis are being performed in the centre's laboratory which is not Clinical Pathology Association (CPA) accredited. (S.7.8.2).
Areas for consideration
The centre are actively pursuing CPA accreditation, a comprehensive action plan was seen to be in place.
Executive recommendations for Licence Committee
None
Evaluation
Some improvement required
Areas not covered on this inspection
Three embryo transfer – this centre is not an IVF centre.

Report compiled by:

Name. Gill Walsh

Designation: Inspector

Date: 16 August 2009

Appendix A: Centre staff interviewed

The Person Responsible and four members of the team.

Appendix B: Licence history for previous 3 years

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0307

Name of PR Dr Nicholas Brook

Date of Inspection 23.7.09

Date of Response 14.9.09

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

Signed…via email

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.

Already highlighted to Gill Walsh (HFEA Inspector) for centre 0307 on 9.9.09

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

I would like to thank the HFEA for their support in re-launching our service here at Southampton. My team has worked tirelessly to restore the Unit to full activity. We very much appreciate the time and effort put in by all both here and at the HFEA in helping us with this process

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

CPA accreditation is due for completion. Progress to full IVF treatment ongoing and Unit build start date April 2010

HFEA Executive Licensing Panel Meeting
23rd October 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Southampton Fertility Unit (0307), Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Brandon Welsh, Head of Audit	Committee Administrator: Joanne McAlpine

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 (30 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 9th September 2009
- Indicative sanctions guidance approved by the Authority on 18th March 2009
- Licence application and any relevant documentation

1. The Panel noted that this centre has been licensed with the HFEA since December 2008 to conduct partner and donor IUI and storage of gametes.

2. The Panel noted that the centre is a small unit based within the Princess Anne Hospital and is part of the Southampton University Hospital NHS Trust.

3. The Panel noted that the centre intends to expand its premises over the next two/three years which will allow the centre to increase capacity and to offer further treatments such as IVF and ICSI.

4. The Panel noted that there is evidence within the report to suggest that the centre has made significant improvement in the following areas:
   - CPA accreditation
   - Patients reporting satisfaction with the treatment that they receive at the centre
   - Implementation of its Quality Management System
   - Comprehensive documentation of a high standard
   - Suitable practices in place in respect of air quality, laboratory, clinical and administrative procedures in relation to licensed treatments

5. The Panel agreed that this centre has improved significantly since the last inspection. Also, in light of the previous licence history the centre was well on the way to being turned around.

6. The Panel noted the very positive response from the PR and commended the inspection team on their efforts in working closely with the centre in order to improve systems and processes.

The Panel's Decision

7. The Panel decided to continue the licence at this time with no additional conditions, and endorsed the inspector's recommendations and that the centre should complete its CPA accreditation by the next inspection.

Signed..... Date...3 November 2009.
Peter Thompson (Chair)