Inspection Report

Date of Inspection: 12-13 January 2011
Purpose of inspection: Renewal of Treatment & Storage Licence
Length of inspection: 15.5 hours
Inspectors: Wil Lenton (WL) HFEA Executive (Lead)
Gill Walsh (GW) HFEA Executive
Andy Leonard (AL) HFEA Executive

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 1 September 2008 and 18 March 2011.

Date of Executive Licensing Panel: 18 March 2011.

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

Centre details

Centre name	Salisbury Fertility Centre
Centre number	0197
Licence number	L0197-8-E
Centre address	Salisbury District Hospital, Odstock Road Salisbury Wiltshire, SP2 8BJ United Kingdom 01722 417 224
Person Responsible	Mr Shaun Fountain
Licence Holder	Dr Lydia Brown
Date licence issued	01 March 2010 (originally 01/05/2006)
Licence expiry date	30 April 2011
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Salisbury Fertility Centre (SFC) was first established as a treatment centre in 2002 and is part of the Salisbury NHS Foundation Trust. There is a satellite service with St Marys Hospital in Portsmouth. The centre relocated to purpose built premises within the same hospital in September 2007.There have been no changes to premises or facilities since the last inspection in June 2008.

Patients are referred from Wiltshire, Hampshire and Dorset Primary Care Trusts which forms 70% of the centres activity: the remaining 30% are self funding patients.

The Person Responsible (PR) is Mr Shaun Fountain, Consultant in Obstetrics and Gynaecology, who has been the lead clinician and PR since the centre opened. Mr Fountain has completed the HFEA PR Entry Programme (PREPT/1094/7), is registered with the General Medical Council and is suitably qualified.

The Licence Holder was changed by the Executive Licensing Panel (ELP) on 11 February 2010 to Dr Lydia Brown, who is a member of the NHS Foundation Trust board.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period (Jan-Dec 2009)
In Vitro Fertillisation	133
Intracytoplasmic Sperm Injection	115
Frozen Embryo Transfer	61
Donor Insemination	1
Intra-Uterine Insemination	44 stimulated 25 non-stimulated

Other licensable activities	
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Outcomes
The centre's live birth rate (LBR*) outcomes are in line with the national average for all treatments and age groups.

*The LBR data was extracted from the HFEA register for the period [Jan 01, 2007 to Dec 31, 2009].
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 licensing decision

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

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

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including 4 major areas of non-compliance and 6 other areas of non-compliance/areas of practice that required improvement.

Since the inspection visit on 12-13 January 2011 the PR has provided information / evidence that, in the view of the inspection team, provides sufficient information to conclude that the centre is now compliant with, or has given a commitment to implement, the following recommendations.

- Review of critical equipment and process validation
- Review of sperm preparation witnessing procedure
- Review of current third party agreement (TPA) documentation
- Accurate reporting of licensed treatment cycles to HFEA Register
- Further development of the quality management system (QMS)
- Development of documentation for the assessment and recording of staff competence
- Update of LBR/success rates on the centre's website
- Risk assess transport of liquid nitrogen from the external reservoir to the cryostore
- Review/amend documentation regarding cleaning of laboratory

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

Recommendation to the Executive Licensing Panel

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

Details of Inspection findings

1. Protection of patients and children born following treatment

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

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

Witnessing and assuring patient and donor identification (Guidance Note 18)
The centre has a standard operating procedure (SOP) in place which describes both the purpose and practice of the critical witnessing processes undertaken during the procurement, processing, freezing, storage and distribution of samples within the centre.
All relevant laboratory staff are trained in the process of witnessing and signed off as competent by the laboratory manager, evidence of which was observed during inspection.
Evidence of witnessing was seen within patient records and found to be compliant with Standard Licence Condition 71, except for the issue mentioned below (SLC T71/33b/15a).

Laboratory witnessing sheets are retrospectively audited annually each February and quality indicators for witnessing have been established and evaluated every quarter (SLC T35/36)

What the centre could do better.

Witnessing and assuring patient and donor identification (Guidance Note 18)
The centre does not ensure that both the operator and witness details are recorded at the completion of the sperm preparation procedure (SLC T71).
No formal assessment of nursing staff competence when undertaking witnessing was evidenced (SLC T15a)

Patient selection criteria and laboratory tests (Guidance Note 11)
Donor recruitment, assessment and screening (Guidance Note 11)

What the centre does well.

Donor recruitment, assessment and screening (Guidance Note 11)
A SOP is followed when selecting and recruiting egg donors (SLC T33b). No sperm donors are currently recruited at the centre.

Quality indicators (QIs) were seen to be in place for the selection and recruitment of egg donors/sharers and an audit was undertaken during 2010 (SLC T35/36).

Donors are selected on the basis of their age, health and medical information provided via a relevant questionnaire and personal interview (SLC T52a). Donor screening was reviewed at inspection and found to be compliant with SLC T52b,e & f. Screening is undertaken in accordance with current professional guidelines in the associated Trust pathology laboratory which is accredited by the clinical pathology accreditation (CPA) scheme (SLC T53a). Procedures were seen to be in place to identify when additional screening is required (SLC T52g)

What the centre could do better.

Donor recruitment, assessment and screening (Guidance Note 11)
No formal assessment/documentation of staff competence when undertaking donor recruitment is in place (SLC T15a).

Donor assisted conception (Guidance Note 20)
Payment of Donors (Guidance Note 13)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

Donor assisted conception (Guidance Note 20)
Following discussions with staff it was established that those receiving treatment with donated gametes are provided with information on the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child (SLC T63a).
Any treatments with anonymous donors are restricted to those for sibling use (SLC T54).

Payment of Donors (Guidance Note 13)
It was confirmed by staff that egg donors are compensated for expenses and loss of earnings in a manner compliant with General Direction 0001. Although evidence for loss of earnings is mentioned in patient information and required, to date only travelling expenses have been claimed and any such receipts retained by the NHS finance department.

What the centre could do better.

Nothing noted

Good clinical practice

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

What the centre does well.

Traceability (Guidance Note 19)
There is a SOP in place to ensure the traceability of all consumable items used in any one treatment cycle. Robust labelling on laboratory consumables, together with witnessing procedures enables all gametes and embryos to be traceable throughout the treatment cycle (SLC T99/101). Such data is electronically stored for a minimum of 30 years (SLC T103). An audit of traceability procedures undertaken at the centre was initially performed in July/August 2007 and QIs for traceability have been established (SLC T36/35).

ICSI (Guidance Note 21)
A SOP was seen to be in place for ICSI (SLC T33b). The process has been validated, and was audited in November 2010. QIs for the ICSI process have been established and are reviewed annually (SLC T72/36/35).

Quality management system (Guidance Note 23)
The centre has a quality management system (QMS) in place to continually improve the quality and effectiveness of the services it provides in accordance with good practice. There is a hard copy of the quality manual within the administration office and an electronic version is accessible to centre staff via a secure server (SLC T32/33a). There is a part-time quality manager in place who coordinates QMS activities. Quality management responsibilities are delegated to specified leads in the administration, clinical and laboratory areas.

Premises – suitability of the premises and air quality (Guidance Note 25)
All activities are carried out on the licensed premises (SLC T1). All licensed premises are located in the same building. A copy of the current centre licence was on display in the patient waiting room (SLC T5). Documented evidence indicating that the processing of gametes and embryos was taking place within a compliant air quality environment was seen (SLC T20)

Equipment and materials (Guidance Note 26)
Maintenance and service contracts were seen to be in place for all critical equipment (SLC T23). Evidence of the monitoring of all critical equipment such as incubators and cryo-dewars was seen to be in place (SLC T24). Any re-usable instruments are thoroughly cleansed, re-packaged and autoclaved via the NHS sterile services department (SLC T28/29). Medical devices are all CE marked where available (SLC T30). The laboratory has an uninterruptible power supply, together with a back-up generator which is tested monthly in order to maintain a continuous power supply.

Adverse incidents (Guidance Notes 27)
The centre has a SOP in place for the reporting of serious adverse incidents to the HFEA (SLC T118).

What the centre could do better.

Validation (Guidance Note 15)
Although some documentation was seen to be in place concerning the validation of laboratory processes and equipment based on templates produced by the Association of Clinical Embryologists, this was not complete to ensure that the process is both logical and evidence based (eg air quality monitoring). No evidence of clinical equipment and /or procedure validation was seen (SLC T24/72).

Quality management system (Guidance Note 23)
Not all activities undertaken at the centre are documented in SOPs. A process mapping exercise may be useful in identifying any centre processes which are not documented in formalised SOPs (SLC T33b).

Not all centre activities have been audited for compliance against approved protocols, regulatory requirements and QIs in the last 2 years (SLC T36) (eg traceability)

A more robust document review and control system needs to be established as during assessment of the system it was seen that some documents had not been reviewed during the last year and that staff had access to superseded documents (SLC T34; Guidance 31.6)

Third party agreements (Guidance Note 24)
It was found that the centre has established some written agreements with third parties who provide goods and services that influence the quality and safety of gametes and embryos. There appeared to be a number of different methods in place to record this information (electronic/hard copy) as well as it being available from different locations (hard copy from administration office; electronic copy from the quality manager or NHS procurement).
This was typified by one copy of a TPA reviewed from the hard copy located in administration which was not signed off by the centre, whereas a signed-off copy was held by the NHS procurement department. It appeared that there was no definitive list of TPAs or set of master copies available. (SLC T111/112/114/115).

Premises – suitability of the premises and air quality (Guidance Note 25)
The cleaning of the laboratory is not documented consistently (SLC T26)

Multiple Births

In 2009 the centre's multiple pregnancy rate was 16.2%

This was below the 30% multiple pregnancy rate target at a statistically significant level.

What the centre does well

In line with General Direction 0003 the centre has implemented a multiple birth minimisation strategy (MBMS) based upon;

- emphasising to all patients the risks of a multiple pregnancy on the health of the babies and the mother;
- advising all patients who meet the criteria for elective single embryo transfer (eSET) to choose that option;
- documenting all occasions where patients choose not to take the medical advice given,
- auditing the centre's results in relation to the number of embryos transferred;
- reporting results of these audits at team meetings;
- reporting up-to-date multiple pregnancy rates to patients;
- campaigning via commissioning Health Authorities for NHS contracts to include funding of all frozen embryo transfers following NHS-funded fresh IVF/ICSI treatment cycles;
- maintaining a pricing structure where embryo cryopreservation and the first year's storage is included in the treatment cycle costs, and frozen embryo treatment cycles are reasonably priced.

In discussions with staff it was stated that the centre continues to monitor/audit/review its MBMS in order to maintain a satisfactory MBR.

Through discussions with staff and examination of documentation it was established that the centre;

- maintains a summary log of cases in which multiple embryos were transferred to patients who met the eSET criteria.
- has documented within the patients notes, the reason(s) why multiple embryos were replaced in cases which met eSET criteria, together with discussions concerning the underlying risks associated with multiple pregnancies.

The centre was therefore seen to be compliant with all requirements of General Direction 0003.

What the centre could better

Nothing noted.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible (Guidance Note 1)
The PR, Mr Shaun Fountain, a General Medical Council (GMC) registered Consultant in Obstetrics and Gynaecology, has been the lead clinician and PR since the centre opened. He is appropriately qualified and experienced for the role and has successfully completed the PR entry programme (PREP-T/1094/7) (SLC T8).

Staff (Guidance Note 2)
The centre provided an organisational chart which clearly defines accountability and reporting structure, together with a staff list with job titles (SLC T11). The centre has access to a registered medical practitioner (SLC T16). Review of staff training log-books revealed that they regularly attend mandatory NHS Trust training and also have access to external training as required. Staff explained that they had access to a variety of professional development activities, including attendance at lectures, online learning, and access to journals (SLC T15).
The centre has assessed workforce requirements against the volume of work undertaken in November 2010 and found that, although both nursing and administrative disciplines were approaching capacity, present staffing levels were still adequate to safely deliver the present workload (SLC T12). Nursing and scientific staff were appropriately registered with their respective professional bodies (Nursing & midwifery Council - NMC/Health Professions Council - HPC)(SLC T14).

What the centre could do better.

Staff (Guidance Note 2)
Not all assessments of staff competencies have been undertaken and documented (SLC T15a) (eg procurement & processing; traceability)

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child (Guidance Note 8)
Via discussions with staff and review of patient notes it was confirmed that before providing treatment services, the centre takes into account the welfare of the child (WoC) who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (SLC T56). A SOP is in place for WoC assessment (SLC T33b) and QIs for WoC assessment are monitored and reviewed (SLC T35). An audit of patient records was undertaken during August 2010 and January 2011 (SLC T36).

What the centre could do better.

Welfare of the Child (Guidance Note 8)
The competence of relevant staff to perform WoC appraisals has not been assessed or documented (SLC T15a)

2. Patient Experience

Focus

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

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

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly (Guidance Note 29)
Via adherence to NHS Trust policies on equality and diversity, harassment and bullying the centre ensures that all treatment services are provided in a non-discriminatory manner and with proper respect for the privacy, dignity, comfort and well being of all current and prospective patients. Each patient is asked to undertake and submit a questionnaire upon completion of their treatment cycle. These questionnaires are reviewed regularly and any issues raised by them are discussed within the team and resolved or further investigated as required.

Counselling (Guidance Note 3)
The availability of the counselling service was evident in the patient information and is documented in the SOP for taking consent. During a review of records it was seen that patients were offered implications counselling and following discussions with staff it was established that implications counselling is offered to patients prior to consent being taken (SLC T60). This is provided by both the clinical staff and an appropriately trained independent counsellor (HF&E Act Schedule 3, S.3(1)a; SLC T15a). There is a SOP in place when providing counselling (SLC T33b). The counselling service was seen to have been audited in September 2010 and the results from the latest 6-monthly user satisfaction survey were due to be collated and assessed later in January 2011(SLC T36). QIs for the counselling service were seen to be in place (SLC T35).

Confidentiality and privacy (Guidance Note 30)
Through mandatory staff attendance at NHS Trust training on confidentiality together with in-house awareness training on the requirements of the HFE Act, the centre ensures that all licensed activities are conducted with proper respect for patient privacy and confidentiality. During the tour of the premises it was demonstrated that patient records are stored securely (SLC T45).

Complaints (Guidance Note 28)
The centre has a documented complaints procedure in place, the details of which were available to patients via the waiting area notice board. The centre has a log of complaints and compliments which was reviewed on inspection. Complaints were dealt with promptly and any learning points discussed at team meetings.

Provision of costed treatment plans (Guidance Note 4)
During discussions with nursing staff it was established that patient treatment costs are discussed in detail between the patient and the nursing team immediately following any clinical consultation, once a firm treatment regimen had been decided upon. Detailed costed treatment plans were seen to be retained within patient records for all usual treatment pathways (Guidance 4.3).

What the centre could do better.

Confidentiality and privacy (Guidance Note 30)
The centre has not undertaken an audit of procedures within the last 2 years to ensure that all information is kept confidential and has not yet established QIs relevant to the maintenance of confidentiality (SLC T36/35).

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information to be provided prior to consent (Guidance Note 4)
An audit of patient information was submitted pre-inspection which covered all treatment regimens. During the inspection patient information sheets were reviewed and seen to provide information about the nature of the treatment, any associated consequences /risks, screening tests required, confidentiality, the need for consent and the availability of counselling (SLC T58).

A SOP was seen to be in place for the provision of information to patients prior to consenting to treatment or donation (SLC T33b). This was also confirmed by discussions with staff and review of patients notes in which checklists were retained, detailing which information had been discussed with patients (HF&E Act, Schedule 3, S.3 (1)b).

Information about legal parenthood (Guidance Note 6)
Staff interviewed were knowledgeable about the requirements for legal parenthood and which patient groups were affected by this legislation. This area was included on the checklist of information held in patient records which is used to document discussions with patients prior to consent being obtained.

What the centre could do better.

Information to be provided prior to consent (Guidance Note 4)
Procedures for taking consent and providing information to patients have not been audited within the last 2 years (SLC T36).

No QIs are in place for the provision of information to patients (SLC T35).

No formal assessment of the competence of relevant staff to provide information to patients has been undertaken and documented (SLC T15a)

No formalised SOP has been documented to describe processes dealing with legal parenthood (SLC T33b).

SFC success rates/live birth rates on the NHS website are presently out-of-date (G4.2e).

Consent

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

What the centre does well.

Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5).
Following discussions with staff and review of patient notes it was confirmed that written consent is obtained from patients/partners and donors prior to any form of treatment service being provided (SLC T57). A SOP was seen to be in place for the process of obtaining consent (SLC T33b). The presence and completion of consent forms was reviewed as part of the notes audit undertaken by centre staff in August 2010 and January 2011 (SLC T36). QIs were seen to be in place (SLC T35). Staff stated that verification of patient identity is sought prior to any consent being signed and is also cross-referenced to patient records prior to procedures being performed. Staff also confirmed that consents were never taken on the day that a procedure was to be undertaken (HF&E Act Schedule 3, S3(1)a)

Consent to legal parenthood (Guidance Note 6)
Staff interviewed were able to adequately describe the requirements for legal parenthood and which patient groups are affected by this legislation. They also stated that at present consent for legal parenthood was undertaken as part of the usual consent procedure and that a legal parenthood checklist was completed as and when required (SLC T60).

Staff were able to adequately describe appropriate actions in the event that the pre treatment checklist indicated that consent to legal parenthood had not been obtained, or had been varied or withdrawn and that treatment would not proceed until any anomalies were rectified / parties informed.

What the centre could do better.

Consent to legal parenthood (Guidance Note 6)
Staff confirmed that presently there is no formalised legal parenthood SOP in place at the centre (SLC T33b/64/65)

3. Protection of gametes and embryos

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

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

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos where created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

Legal Requirements
Licensed activities take place only on licensed premises. The inspection team reviewed the centre's activities and concluded that all gametes and embryos are procured and used in a lawful manner, with appropriate consent, for activities approved by the centre's licence.

In-house training and ongoing continuing professional development (CPD) activities are used to develop and/or maintain staff respect for the special status of the embryo when undertaking ART treatment services.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

Storage of gametes and embryos (Guidance Note 17)
A detailed SOP is in place defining processes for the storage of gametes and embryos (SLC T33b). QIs have also been developed (SLC T35). Junior scientific staff competence when undertaking storage of licensed material is assessed and documented (SLC T15a). When cryostorage records and dewar audits were reviewed it was found that all currently stored material was within its statutory storage period and there was a 'bring forward' system in place to ensure that samples were not stored beyond their consented storage period. (HF&E Act 14(1)(c). Prior to storage all gamete providers are screened for HIV 1&2, Hep B&C (SLC T50a). There is also a quarantine tank for the storage of samples awaiting the results of screening tests.

What the centre could do better.

Storage of gametes and embryos (Guidance Note 17)
Storage processes have not been validated (SLC T72)
Storage procedures have not been audited against compliance with approved protocols the regulatory requirements and QIs in last two years (SLC T36).
The competence of senior scientific staff when undertaking storage of licensed material has not yet been assessed and documented (SLC T15a).
The suitability of practices involved in the transportation of liquid nitrogen from the external reservoir to the cryostore could not be confirmed. Presently this potentially hazardous task is undertaken by only one staff member. The centre may need to risk assess present practice and consider whether this task should be undertaken jointly by two staff members (CoP Guidance 25.14, HF&E Act 17(1)d).

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*

What the centre does well.

Distribution of gametes and embryos (Guidance Note 15)
The centre has procedures in place to ensure that gametes/embryos are only transferred to/from other licensed centres under conditions that maintain their quality and safety.

A SOP is in place for the transfer of licensed material between UK HFEA licensed centres (SLC T33b). The SOP details all documentation/information required to be in place prior to the receipt/dispatch of licensed material. A shipping label giving the required transfer details/information is affixed to the centre's container prior to dispatch (SLC T107).

All licensed material is packaged/transported in a container that is designed for the carriage of biological materials and which minimises the risk of contamination whilst preserving their biological function (SLC T105; 106)

The centre did not undertake any import/export of licensed material from/to the UK in the period 1 January to 31 December 2010.

What the centre could do better.

Nothing noted

Use of embryos for training staff (Guidance Note 22) – *only applicable for centres which use embryo to train staff*

What the centre does well.

Use of embryos for training staff (Guidance Note 22)
The centre ensures that embryos are only used for purposes such as training staff in embryological techniques, when both gamete providers have consented to such use. Trained nursing staff ensure that patients are informed about the types of training undertaken prior to consents being signed. Appropriately signed consents for the use of embryos in training were seen in patients notes (SLC T94). A log of all embryos used in training is kept to ensure that no embryos used in training are subsequently used for patient treatment and that numbers used are kept to a minimum (SLC T92/96).

What the centre could do better.

Nothing noted.

4. Good governance and record keeping

Focus

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

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

▶ **Record keeping** • Record keeping and document control (Guidance Note 31)
What the centre does well. **Record keeping and document control (Guidance Note 31)** All patient/partner and donor records were seen to be stored securely. Those reviewed during the course of inspection were considered to be well organised, clear and legible and seen to contain appropriate documentation as required (SLC T46/47), such as; • patient/donor identification • surname, first name, date of birth, age & gender • treatment services provided • relevant medical history • WoC assessments • relevant consents • relevant laboratory test results
What the centre could do better. Nothing noted

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

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

What the centre does well.

Obligations and reporting requirements of centres (Guidance Note 32)
Prior to inspection the PR/centre provided all the information required under General Direction 0008, paragraphs 2 & 16. During the inspection process all members of staff cooperated fully with the inspection team. Information requested both at the time of the inspection and subsequently was provided in a timely manner.

During the last financial year (April 2009 to March 2010) the centre took an average of 28 days to pay invoices. The licence renewal fee was paid in September 2010 (SLC T9d).

What the centre could do better.

Obligations and reporting requirements (Guidance Note 32)
Licensed Treatment Reporting
To determine whether all licensed treatments are reported to the HFEA as required by Direction 0005, a sample of licensed treatments undertaken by the centre between 01/12/2009 and 30/11/2010 was reviewed. The sample was drawn from the centres records and was reviewed against an extract of the Authority's statutory register.

The sample comprised 151 treatments (i.e. 134 IVF and 17DI treatments) and was drawn from the centre's laboratory records (i.e. Egg Log and IUI Folder).

- Less than 1% (1/134) of the IVF and approximately 12% (2/17) of the DI treatments in the audit sample were found to be unreported to the HFEA at the time of inspection.
- On average only 65% of the 151 treatment cycles audited had been reported to the HFEA within five working days contrary to General Direction 0005.
- A significant proportion (i.e. 35%) of the treatments undertaken within the 12 month sample period was reported late.

Data Quality
To ascertain the quality of data submitted by the centre for inclusion on the statutory register, 78 sets of assorted form data submitted to the HFEA between 1 December 2009 and 30 November 2010 were reviewed against source documentation held on patient and donor files. It was found that 19% (15/78) contained errors or omissions.

- One error was found in a critical field that could affect the Authority's ability to fulfil it's statutory obligations to offspring (i.e. failure to indicate the use of donor gametes in an IVF treatment).
- An error in patient identifying information (date of birth) was also found.

These observations indicate that the centre is non-compliant with General Direction 0005 and SLC T9e.

5. Changes / improvements since the previous inspection on 11/06/2008

Area for improvement	Action required	Action taken as evidenced during this inspection
It was observed from laboratory records that the placing of samples into storage is occasionally witnessed retrospectively.	Guidelines require that all witnessing of procedures shall be completed and recorded at the time the clinical or laboratory process/procedure takes place. The PR should review witnessing procedures in consideration of HFEA guidelines. Where procedures deviate from guidelines, the risks of the practice should be assessed and documented.	This witnessing issue has been resolved.
It was noted during inspection that not all agreements have been finalised with two companies providing consumables used in the laboratory.	The Centre shall establish a written agreement with a Third Party for external activities which influence the quality and safety of gametes and embryos procured or processed.	Different issues to be resolved concerning TPA.
It was observed on inspection, and in discussion with staff, that the emergency resuscitation bag in the treatment room had not been checked regularly. The Salisbury NHS Foundation Trust has a policy which states that emergency equipment should be checked by staff weekly.	It was recommended that there should be documented evidence that all emergency equipment is checked in accordance with Trust policy. Resuscitation Guidelines UK[1] state that the responsibility for checking resuscitation equipment rests with the department where the equipment is held and checking should be audited regularly.	Issue resolved.
It was noted at the time of inspection that there were differences between embryologists in the reporting of ICSI outcomes.	It was recommended by the inspector that for the purposes of clarity and continuity that the consistency of reporting should be reviewed.	Issue resolved.

(1) Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London, The Intensive Care Society, The Resuscitation Council (UK), October 2004.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None Noted					

Major area of non compliance

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

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Operator and witness details are not recorded at the completion of the sperm preparation procedure	T71	The centre should ensure that both operator and witness details are recorded at the completion of the sperm preparation procedure	Immediately	Done on13/01/11 – additional "witnessing boxes" to collect this record on all relevant laboratory sheets	Issue resolved.
Not all clinical and/or laboratory equipment/processes have been appropriately validated.	T24/72	The centre should complete laboratory and clinical process and equipment validation.	3 months from ELP minutes being published	This item was already flagged for completion. Work which has been in progress over last 2 years is to be completed over next 3 months	Issue being addressed. Review as part of ongoing monitoring.
Not all licensed treatment cycles are being reported accurately to the HFEA Registry.	T9e	All licensed treatment cycles should be reported accurately to the HFEA.	Immediately	Staff aware, action already in place which is effective and has addressed the late reporting of cycles.	Issue addressed. Liaise with Registry as part of ongoing monitoring.

Some TPAs are not compliant with all standard licence conditions.	T111/112/ 114	TPAs to be reviewed and updated to ensure they are compliant with all standard licence conditions.	3 months from ELP minutes being published	The inspection has highlighted to the Trust the requirement for SFC to have a more proactive system in place for handling TPA's which is currently handled by the Trust Procurement office. To be completed over next 3 months	Issue being addressed. Review as part of ongoing monitoring.

Other areas of practice that requires improvement

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
The QMS is not fully developed in the following areas; • SOPs • Audits • QI • Document control & review	T33b/T36 T35/T34	SOPs should be formalised to cover all centre activities. Audits of all centre activities should be undertaken at least every 2 years. Quality indicators should be developed for all centre activities. A more robust document control and review system needs to be established.	6 months from ELP minutes being published	Review of QMS function is flagged for detailed analysis in 2011. ***(continued below)***	Issues being addressed. Review as part of ongoing monitoring.
Staff competence to undertake certain key activities has not been assessed or documented.	T15a	Documentation showing assessment and recording of staff competence when undertaking centre activities.	3 months from ELP minutes being published	Further development of existing practices for competence assessment.	Issue being addressed. Review as part of ongoing monitoring.
No definitive up-to-date list of services/products supplied by third parties is in place.	T115	An up-to-date list of services/products supplied by third parties should be in place.	Immediately	The centre is currently reviewing the arrangements for TPAs	Issue being addressed. Review as part of ongoing monitoring.

SFC success rates/live birth rates on the NHS website are presently out-of-date.	G4.2e	Update of SFC success rates/live birth rates on NHS website to include most recent verified data.	Immediately	As explained at inspection, this was in hand but not complete due to IT issues. New website will go live by 4th March 2011.	Issue resolved.
The risks of practices involved in transporting liquid nitrogen from the external reservoir to the cryostore Has not been assessed.	G25.14	Risk assess transport of liquid nitrogen from reservoir to cryostore in order to ensure staff safety.	Immediately	Risk assessment completed	Issue resolved.
The centre does not maintain a consistent record of laboratory cleaning .	T26	The centre should review/amend documentation of laboratory cleaning to ensure better consistency.		All scientific staff made aware of the requirement to record cleaning in the "Changes" diary – clarified in "laboratory routines" procedures.	Issue resolved.

Additional information from the Person Responsible
Review of QMS Develop the “Quality Team” so that the qualified Quality Manager devolves the day-to-day management of the QMS. Consider the pro’s and con’s of QMS software (QPulse) compared with further development of the existing QMS structure Gap analysis/audit of existing SOP’s with Code of Practice to ensure all Centre activities are documented Audit of “audit cycle” to ensure all audits are scheduled Quality indicators are in place in line with the HFEA model document – ensure this matches the requirements for all Centre activities to be covered **Review of document control mechanisms** The specific weaknesses of the document control system identified during the inspection arose due to new staff “finding things” for the inspection team. This highlights the need for additional training in QMS and document control, and additional work on the archiving of out-of-date documents. Staff should be aware of the importance of the “review date” which is present on all documents. In day-to-day practice, these problems would not arise.

HFEA Executive Licence Panel Meeting

18 March 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0197 (Salisbury Fertility Centre) – Renewal Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that the centre was first established as a treatment centre in 2002 and is part of the Salisbury NHS Foundation Trust. The Panel noted that the centre operates a satellite service with St Mary's Hospital, Portsmouth.

2. The centre relocated to purpose-built premises within the same hospital in September 2007, and there have been no changes to the premises or facilities since the last inspection in June 2008.

3. The Panel noted that patients are referred from Wiltshire, Hampshire and Dorset Primary Care Trusts which forms 70% of the centre's activity: the remaining 30% are self-funding patients.

4. The Panel noted that the Person Responsible (PR) is a Consultant in Obstetrics and Gynaecology and has been the lead clinician and PR since the centre opened.

5. The Panel noted that the PR has completed the PR Entry Programme, is registered with the General Medical Council and is suitably qualified.

6. The Panel noted that, on 11 February 2010, it had approved a variation of licence at the centre for a change of Licence Holder to Dr Lydia Brown, who is a member of the NHS Foundation Trust Board.

7. The Panel noted that the centre's renewal inspection took place on 12 and 13 January 2011, within the second financial year following the previous inspection, in accordance with the HFEA Compliance and Enforcement Policy..

8. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and six other areas.

9. The Panel noted that since the inspection visit the PR has provided information/evidence that, in the view of the Inspectorate, is sufficient to conclude that the centre is now compliant or has given a commitment to implement the recommendations within the report.

10. The Panel noted that the PR in his response has given a clear commitment to implement all of the recommendations on page 10 of the inspection report, and that some of these areas have already been implemented.

11. The Panel noted that the centre has made good progress to reduce its Multiple Birth rate to 16.2%, which is significantly below the 30% multiple pregnancy rate target in force at the time and in line with General Direction 0003.

12. The Panel noted the recommendation from the Inspectorate to renew the centre's licence for a period of four years with no additional conditions.

13. The Panel noted that the application for the renewal of the licence was not submitted by either the (PR) or the Licence Holder (LH), as specified in the HFE Act 1990 (as amended). The Panel therefore requested confirmation in writing from either the PR or the LH that they wish to proceed with the renewal of the centre's licence, and to send this to the Inspector responsible for the centre.

14. The Panel noted that not all licensed treatment cycles are being reported to the HFEA in the required timeframe.

15. The Panel noted the PR's response to the Inspector's recommendation about the reporting of treatment cycles. However, it was not fully reassured by this response and urged the PR to ensure that all treatment cycles are reported to the HFEA immediately, including all those that may still be outstanding.

Decision

16. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information as required by General Direction 0008. However, the Panel requests that the PR or LH confirms that they agree to renew the centre's licence.

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

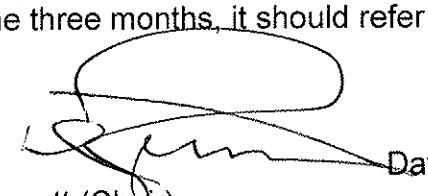
18. The Panel was satisfied that the licence renewal application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

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

20. The Panel was satisfied that the application does involve the use of embryos for training purposes for embryological techniques, when both gamete providers have consented to such use.

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

22. The Panel therefore agreed to renew the centre's licence for a period of four years with no additional conditions. However, the Panel requested the PR to assure the Inspectorate that he has submitted the outstanding reports of treatment cycles to the HFEA within three months of this meeting. If the Inspectorate is not satisfied with the progress made on this by the PR within the three months, it should refer this back to the Panel.

Signed:  Date: 28 March 2011

Mark Bennett (Chair)