Inspection Report

Date of Inspection: 10 May 2011
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 9.25 hours
Inspectors Chris Hall
Ellie Suthers
Sara Parlett
Roz Shaw-Smith
Cathy Hodgson

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 18 March 2010 and 8 July 2011

Date of Executive Licensing Panel: 22 July 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	The Woking Nuffield Hospital
Centre number	0144
Licence number	L0144-11-B
Centre address	Assisted Conception Services, Victoria Wing, The Woking Nuffield Hospital, Shores Road, Woking, Surrey, GU21 4BY
Person Responsible	Mr Andrew Riddle
Licence Holder	Mrs Caroline Lewis
Date licence issued	5 July 2007
Licence expiry date	31 October 2011
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The assisted conception unit is based in the Victoria Wing of the Nuffield Health, Woking Hospital, Surrey. It has a good history of compliance with no previous additional conditions on its licence.

The centre offers a complete range of assisted reproductive treatments, including ovulation induction, intrauterine insemination (IUI), in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). The centre provides both NHS and self-funded treatments. Currently approximately 1400[1] treatment cycles are carried out per year.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 April 2010 to 31 March 2011
In vitro fertilisation	689
Intra cytoplasmic sperm injection	423
GIFT	0
Frozen embryo transfer	180
Donor insemination	22
Egg share provider (sharer)	13
Egg share recipient	0
Egg donation (non-egg share)	17
Intra uterine insemination	48 *01/01/2010 -31/12/2010

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period 01 April 2010 to 31 March 2011 show the centre's success rates are in line with national averages with the following exceptions:

Success rates for ICSI cycles using fresh embryos created from patients' eggs for the 16-37 age group are above the national average; and

Success rates for FET cycles for the 16-39 year-old age group for the above period are below the national average (see page 10).

[1]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 he has 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; and
- 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 seven major areas of non-compliance and seven other areas of non-compliance or areas of poor practice.

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

Major areas of non compliance:

- The PR should ensure that all documented competence assessments are in place for all staff that undertake witnessing.
- The PR should ensure that the centres audits of traceability include an element of checking of consumables in use in the lab to the centre's IT system record.
- The PR should review the appropriateness of the current frequency of critical parameter monitoring of laboratory equipment and inform the Executive.
- The PR must take appropriate action regarding the continued storage of embryos stored without valid consent and inform the Executive of the action taken immediately.

Other areas of practice that require improvement:

- The PR should ensure that the summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer is kept as set out in the centre's multiple birth strategy.
- The PR should ensure there are written procedures for staff to follow and refer to in relation to legal parenthood.
- The PR should ensure the Laboratory Manual is revised to reflect authorised uses of embryos only.
- The PR should ensure that the centre's recall procedures is documented and available for staff reference.
- The PR should ensure that the traceability SOP is revised to include the requirement that all equipment used is recorded.

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

Major areas of non compliance:

- The PR should submit an action plan, including a summary of all procedures that require validation and timeframes for completion.
- The PR should ensure that diagnostic semen assessment is conducted in a laboratory with Clinical Pathology Accreditation (CPA) UK Ltd accreditation.
- The PR should ensure that a third party agreement is put in place with the courier company used to distribute gametes.

Other areas of practice that require improvement:

- The HFEA has recently sought and obtained expert opinion on HTLV-1 screening and have released sector guidance. The PR should conduct a risk assessment to determine the requirement for HTLV-1 testing prior to storage.
- The PR should ensure that payment of HFEA invoices is made within 28 days of the invoice date.

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 the recommendations made in this inspection report, has either already addressed or has committed to addressing them within the timeframe set out in this 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.

Contemporaneous witnessing is undertaken and recorded at each critical point of clinical and laboratory processes by two members of staff to ensure patients receive treatment using the correct gametes or embryos. The witnessing record contains the initials of the individuals performing and witnessing the procedure and the witnessing record is retained in patient/donor files. The centre's 'unit staff signature log' lists the name, status, initials and signature of all members of staff (Standard Licence Condition T71).

A comprehensive witnessing SOP is in place. Where witnessing stages are not included in the SOP (e.g. for IUI) these were seen to be embedded within the appropriate process SOP (Licence Condition T33b).

Relevant quality indicators (QI's) have been established (Licence Condition T35). It was confirmed via discussion with the embryology manager that witnessing procedures are audited monthly and the findings have been documented and, where appropriate, corrective actions implemented. (HF&E Act 1990 (as amended), Schedule 3A (10); Licence Condition T36)

Six sets of patient notes were reviewed at the time of inspection. All witnessing records were found to be present and appropriate in respect of gametes and embryos procured and processed. The date and time for each witness step were recorded (Licence Condition T71 and CoP Guidance 18.7 (b)).

Evidence of competence assessment of staff performing witnessing steps was seen, with one exception documented below (Licence Condition T15 (a))

What the centre could do better.

Administrative staff may undertake witnessing duties on occasion, but competence assessments have not been documented for these staff (Licence Condition T15 (a)).

Patient selection criteria and laboratory tests (Guidance Note 11)

The centre has SOPs in place which describe patient referral, initial consultation and case review processes. On the day of inspection it was confirmed via review that QIs have been established for patient assessment and treatment and via discussion with the Quality Manager that the centre undertakes a monthly medical record audit of 10 patients assessment and treatment. We reviewed the documentation of one audit, its findings and action (Licence Condition T49).

An audit of patient files on the day of inspection found that they record the reason(s) for treatment, record medical history and the results of laboratory tests and other investigations.

Laboratory tests, with one exception (see below) are performed by appropriately accredited laboratories (Licence Condition T21).

What the centre could do better.

Diagnostic semen analysis is not undertaken within a laboratory with CPA (UK) Ltd or equivalent accreditation (Licence Condition T21).

Donor recruitment, assessment and screening (Guidance Note 11)
Donor assisted conception (Guidance Note 20)

Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

The assisted conception services (ACS) manager stated that the centre only uses donor gametes from identifiable donors in treatment. The centre provides treatment with egg sharers, (including altruistic egg donors) and undertakes some sperm donor recruitment.

Patients are responsible for identifying their own sperm donor and concluding purchasing arrangements where sperm is to be imported. The centre handles the transfer arrangements

The centre has a SOP which describes the donor recruitment and selection process to be followed by staff. (Licence Condition T33b)

The ACS manager confirmed that QIs relevant to the recruitment and selection of donors have been established (Licence Condition T35) and that audits of compliance with the

SOP and QIs has been undertaken and that audit findings and corrective actions are documented and corrective actions implemented (Commission Directive 2006/86/EC, Appendix 1 F).

An audit of four donor records on the day of inspection provided evidence that donors are selected on the basis of age, physical examination and medical history. Prior medical history is established via questionnaire and interview and appropriate screening tests are conducted within appropriately accredited laboratory facilities (Licence Conditions T52(a), (b) and T53(a)). The audit also confirmed that donors are rescreened 180 days after donation (Licence Condition T53 (c)).

The senior nurse explained that donors can formally indicate their wish to receive information on the outcome of their donation. The centre can provide donors with information on the sex, year of birth and the number of children born as a result of their donation in such cases (HF&E Act 1990 (as amended) 31ZD(3)).

There is policy for reimbursing donors for loss of earnings but the centre staff have never been asked to do so. The centre does reimburse expenses though it is reported to be rare that donors ask for reimbursement. Where expenses are paid for travel and parking expenses a cumulative record is maintained in patients file (Direction 0001)

The centre provided documented evidence from third parties that overseas donors have not received more than the prescribed amount of compensation (Direction 0001).

What the centre could do better.

Nothing noted at time of inspection.

Good clinical practice

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

What the centre does well.

Clinical pregnancy rates
HFEA held register data for the period 01 April 2010 to 31 March 2011 show that the centre's clinical pregnancy rates are in line with national averages, except for:

- ICSI cycles using fresh embryos created from patients' eggs for the 16-37 age group which was above the national average; and

- frozen embryo transfer (FET) cycles for the 16-39 year-old age group which was below the national average.

The PR provided evidence to show that the centre's audit and monitoring processes identified the 16-39 year-old FET cycle clinical pregnancy rates. Investigation and corrective action has been taken but the PR has not yet established the root cause. The PR has indicated that this will continue to be closely monitored and that further investigation was planned.

Quality management system(Guidance Note 23)
The quality management system (QMS) is comprehensive and facilitates continuous improvement in the quality and effectiveness of the services that the centre provides.

The QMS was discussed with the quality manager (QM). Review of quality management documentation established that SOPs and QIs have been developed for licensable activities; audit of practice is undertaken; corrective actions are implemented as required; and there is regular reporting to centre management (Licence Condition T32)

There is an annual review of quality management system by the management team. The next meet was due to take place in the month of inspection (NB. this meeting had been pushed back from November 21010 because of staff sickness absence).

The QM confirmed that quality management is discussed at management team meetings on a roughly quarterly basis and sooner if appropriate in response to alerts, incidents, KPI's and QI's (Licence Condition 35).

The QM confirmed that there is an annual audit programme and that additional audits are conducted as follow-up of corrective and preventative action plans (capa) put in place following a complaint or incident (Licence Condition T36).

We reviewed the KPI quarterly results for 2010 and the quality protocol and observed that meetings at which quality management is discussed are minuted. In addition we saw evidence that notes audits are performed on a monthly basis and that embryo thaw rates are audited quarterly.

Staff maintain their own training folders which detail mandatory training, competences and practical class room training sessions. The folders are reviewed on a random basis by the QM.

Traceability (Guidance Note 19)
There is a traceability SOP in place and related QIs have been established. The embryology manager explained that a traceability audit had recently been conducted and the report was pending at the time of inspection. (T33; T35)

It was confirmed via discussion with the Embryology Manager that procedures are in place to ensure traceability data is stored for 30 years. (T103)

Process Validation (Guidance Note 15)
The embryology manager confirmed process validation was being undertaken using the

Association of Clinical Embryologists (ACE) template, but has not been completed (Licence Condition T72)

Equipment and materials (Guidance Note 26)
Laboratory staff provided documented evidence of regular cleaning of equipment (Licence Condition T26).

The laboratory manager confirmed that incubators and dewars are monitored continuously and linked to an auto dial out alarm. Evidence of daily checks of the temperature and CO2 concentration of incubators and temperature of the laboratory fridge were reviewed.
The laboratory manager provided evidence that equipment is serviced on a regular basis and electrical safety testing was last performed in November 2010.

Critical equipment has been validated, using the ACE equipment qualification review template. Validation records for one hood were reviewed and included a review of the service history and monitoring results (Licence Condition T24). It was observed that equipment with critical measuring functions are calibrated against a national standard. The laboratory manager confirmed that equipment would be revalidated following repair (Licence Condition T26).

The centre has instruction manuals and SOPs for operating critical equipment. A SOP was seen to document the action to be taken in the event of malfunction or failure of equipment (Licence Condition T27).

The laboratory manager stated that CE marked consumables are used where possible, this was confirmed by a sample of consumables seen in use in the laboratory.

Premises suitability and air quality (Guidance Note 25)
Laboratory records documenting the performance of regular cleaning activities were seen
The air quality monitoring SOP, documenting the requirement for monthly particle counts and six monthly settle plate testing and the locations for monitoring, was reviewed during the inspection. Recent air quality monitoring results demonstrated Grade D background and Grade A in the critical environment. Evidence of corrective action taken based on results obtained was seen (Licence Condition T20).

Adverse Incidents (Guidance Note 27)
Incidents are reported to the HFEA and the centre's management team and there is an incident reporting SOP in place for staff to follow.

The QM oversees incident investigation and the development of corrective and preventive action plans in response to incidents.

An HFEA Incident Report Form reviewed at the time of inspection confirmed that the particular incident had been investigated, corrective action had been identified and documented, and the action implemented.

Third party agreements (TPA) (Guidance Note 24)
It was observed that the there are written third party agreements in place with companies that provide goods and services that may influence the quality and safety of gametes and

embryos (Licence ConditionT111b) and a list of TPAs in place has been compiled (Licence Condition T115).

Five TPAs were audited during the inspection. TPAs were found to meet relevant requirements (Licence Condition T114)

What the centre could do better.

Traceability (Guidance Note 19)
The centre's traceability SOP does not include the requirement to record all critical equipment used. Nevertheless, a review of traceability records on the day of inspection found that all equipment used is recorded in practice. (T99)

A spot check of three consumables in use in the laboratory against that recorded as being in use on the centre's database was performed on inspection. One of the consumables in use had not been correctly recorded on the database. (T102). The QM confirmed that audits of consumables in use versus those recorded as being in use are not undertaken (Licence Condition T36).

Validation (Guidance Note 15)
At the time of inspection critical procurement and processing procedures had not been validated. The Embryology Manager confirmed plans to complete process validation using the Association of Clinical Embryologists (ACE) validation template within six months.(T72)

Equipment and materials (Guidance Note 26)
Heated stages and transport incubators are serviced annually and temperature mapping is also performed annually. No other independent monitoring of this equipment is performed (Licence Condition T24).

Premises suitability and air quality (Guidance Note 25)
The Embryology Manager confirmed that diagnostic semen assessment is performed at the centre. The laboratory is not accredited by CPA (UK) Ltd.. The PR indicated that he felt National External Quality Assessment Service (NEQAs) was more appropriate (Licence Condition T21).

Third party agreements (Guidance Note 24)
There is no TPA in place with the courier company used by the centre. (Licence Condition T111 (b)).

Multiple Births (Guidance Note 7)

The centre's multiple pregnancy rate for 2009 was 20.1% with an elective single embryo transfer rate of 8.3% for the same time period[1].

[1] *This data was extracted from the HFEA's Register data as at 23/06/2010. At this time the HFEA had performed a preliminary validation process in which centres were asked to confirm the accuracy of*

What the centre does well

The centre's multiple pregnancy rate is significantly below the 2008/2009 multiple pregnancy rate target of 30%[2] at a statistically significant level.

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003. The PR described progress towards reducing multiple pregnancy rates and subsequent multiple birth rates. The strategy and protocols have been audited as part of the quality management audit programme. A review of the strategy is planned for the month following inspection.

The PR confirmed that information concerning the risks associated with multiple births is discussed with patients prior to treatment and the fact that risks have been is recorded in the patients notes (Directions 0003).

Two logs are maintained with summary information on each multiple embryo transfer conducted (Directions 0003).

What the centre could better

A summary log of multiple embryo transfers recording patients that meet the centre's criteria for elective single embryo transfer (eSET) but who elect not to have it, is not maintained in the prescribed format (i.e. detailing eligibility, the reason for variation from the single embryo transfer policy and outcomes) (Directions 0003).

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, a General Medical Council (GMC) registered consultant in Obstetrics and Gynaecology, is appropriately qualified and experienced for the role and has successfully completed the PR Entry Programme (T8).

All medical activities are overseen by the PR and three other medically qualified staff seven days a week. The PR is contactable by phone and pager at anytime. (T16)

An organisation chart that defines areas of staff responsibility and lines of staff accountability was provided with pre-inspection documentation. (T11)

The QM produces an analysis of activity and capacity on a monthly basis and this is

information on treatment cycles carried out up to and including 30/06/2009 for pregnancy outcomes and 30/06/2008 for live birth outcomes. Some of the information used in this analysis may be subject to change.

[2] *A multiple pregnancy rate of 30% has been calculated as likely to be equivalent to a 24% multiple birth rate.*

reviewed by the management team. (T12) The PR confirmed that there are sufficient embryology and medical staff for current levels of activity but that the centre's monthly monitoring activity and capacity did indicate a short-fall in nursing staff. Activity levels are being maintained by nursing staff managing their hours. The PR confirmed that he was actively investigating how this shortfall can be addressed (Licence Condition T12)

The PR confirmed that the centre has no staff turn-over issues and that to date the centre has not experienced problems in recruiting suitably qualified and experienced staff to posts.

Staff (Guidance Note 2)
The centre has suitably qualified staff to carry out the services offered. Where appropriate, staff were seen to be registered in accordance with relevant professional and/or statutory bodies (T14).

Appropriate checks are undertaken to assure the PR that employees are of suitable character. Hospital controlled processes ensure employee references are taken up and Criminal Records Bureau checks are made for all members of staff (HF&E Act 1990 (as amended), Section 17 (1) (a)).

The hospital and centre operate a new staff induction processes. We observed documentation of an embryologist's induction programme at the time of inspection (Licence ConditionT15)

Competency assessments for medical, embryology and nursing staff were observed on the day of inspection (Licence Condition T12; and T15a). Additionally documentary evidence of staff undertaking continuing professional development (CPD) activities was observed.

The hospital operates a formal training programme for manual handling and health and safety training, and an annual appraisal process (Licence Condition T15 (c); T15 (d))

Counselling (Guidance Note 3)
The centre offers counselling to all clients and includes those providing consent and those with parenthood issues. (HFEA Act 1990 (as amended), Schedule 3Z part 2 and 3ZA part 2). Mandatory counselling is provided to those receiving and donating genetic material. (HFEA Act 1990 (as amended), Schedule 3, S3(1)(a)).

The centre has arrangements in place for specialist counselling referral when appropriate. This is provided by the British Association of Counselling and Psychotherapy, and the Royal Surrey Hospital with which the centre has an agreement to provide oncology and genetic counselling.

The counsellor was not accredited by the British Infertility Counselling Association (BICA) at the time of inspection, but she provided documentary evidence that accreditation was pending following review of CPD documentation by BICA. The counsellor expects accreditation to be awarded during July 2011 (2.12(b)).

There is a counselling SOP in place and relevant QIs have been developed. Patient

evaluation questionnaires are also used and were observed on inspection.
What the centre could do better. Nothing noted at the time of inspection

Welfare of the Child (Guidance Note 8)
What the centre does well. Via our discussion with staff and review of four patient files, evidence was provided to show that before providing treatment services, an assessment is made of the welfare of the child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth (Licence Condition T56). There is a welfare of the child SOP in place and compliance is monitored via a monthly audit of ten patient records against the relevant QI (Licence Conditions T33b; and T35). The SOP details action staff should invoke should they feel that it may be inappropriate to proceed with treatment (i.e. discussion at multi-disciplinary staff meetings; seeking additional information; use of counselling; and ethics committee referral).
What the centre could do better. Nothing noted at the time of inspection.

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.

In addition to our discussions with the PR, ACS manager, QM and senior nurse during the inspection, an interview was held with a patient and her partner. In the above discussions assurances were given with regard to respect for the privacy, confidentiality, dignity and the comfort of patients and donors.

The centre actively seeks patient feedback by survey and evidence was observed that it investigates patient complaints and takes action to address them where appropriate. Evidence of complaints having been investigated and resolved was observed at the time of inspection.

The patients waiting room has a 'Complaints procedure' notice on the wall. The notice provides contact details for the hospital matron as the primary contact for complaints, but there are also contact details provided for the Care Quality Commission and HFEA.

The centre has a 'Handling complaints' SOP for staff reference and which details timeframe within responses to complaints must be made and a mechanism for recording the nature of the complaint, investigation, resolution and whether the hospital general manager and HFEA need to be advised of the complaint.

The centre provides private patients and their partners with a price list detailing the costs of consultations, investigations and any extra costs. A separate price lists records drug costs. Price lists are also available in the patient waiting room. The patient and where relevant their partner are given the opportunity to discuss costs before treatment. (Guidance Note 4.3)

The centre has an egg sharing scheme. The senior nurse provided evidence to show that egg sharers are screened in accordance with legal requirements and are registered with the HFEA as donors and their fitness for the process is both medically and psychologically assessed. The senior nurse provided evidence to show that egg sharers and recipients undergo mandatory counselling.

An audit of sharer and recipient records confirmed that separate agreements with the egg provider and recipients are consistent with each other (Guidance Note12.13) that there is appropriate consent, that appropriate screening is conducted and that agreements meet the requirements of Guidance Note 12.

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytroplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Patient information documentation submitted pre-inspection was found to provide appropriate information about the nature of the treatment, consequences and risks, analytical tests, confidentiality, consent, and the availability of counselling Licence Condition T58). A checklist for providing information was observed in patient notes reviewed during the inspection. Patients and partners both sign the checklist acknowledging receipt of information.

Patients and their partners (where relevant) have a two hour information consultation with a nurse where they are encouraged to ask questions and discuss their proposed treatment in detail. They are then asked to attend a second appointment to sign the relevant consent forms. The senior nurse explained that this is in order to provide the patient and partner sufficient time to consider their consent to treatment.

A patient and her partner interviewed during the inspection both commented favourably on the patient information they had received prior to providing consent.

There is a SOP in place covering the provision of information and relevant QIs have been established. Evidence of monthly audits of information provision checklists in patient notes was reviewed. Patient and partner satisfaction with information provision is also canvassed by survey. Patients are asked on the survey of they feel that sufficient information has been provided. 100% said yes.

What the centre could do better.

Nothing noted at time of inspection.

Consent

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

What the centre does well.

Written consent is obtained from patients prior to treatment being provided (Licence Condition T57).

The senior nurse confirmed that patient identity is verified at the first visit to the centre and patient records contain photographic identification to assist subsequent positive identification. The senior nurse described in detail the process that staff follow to check the identity of the patient at the time of each consultation, including prior to taking consent, conducting investigations and treatment.

There is a consent SOP in place and relevant QIs have been established. Evidence of monthly record audits being conducted and findings being documented and followed up was reviewed. (Licence Condition T33b; T35; T36; and T15a) The senior nurse provided evidence to show that 40 patient records are audited for completeness and accuracy. Any errors or omissions are discussed at team meetings and with the individuals involved and corrective actions take. Corrective actions are documented in team meeting minutes. Five sets of patient and donor records were reviewed during the inspection and found to be accurate and complete.

Evidence of legal parenthood being addressed within information provided to patients/partners prior to consent was reviewed. Additionally, via an interview with a patient and her partner we were able to confirm that information on legal parenthood is provided at different points by both nursing and counselling staff.

What the centre could do better.

At the time of inspection there were no written procedures relevant to legal parenthood available for staff reference (i.e. either as a stand-alone document or as a component of consent procedures). (T33(b))

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.

The activities authorised by the centre's licence are carried out at the premises specified in the licence (T1) and the licence certificate is on display within the centre. (T5)

From the evidence provided during inspection and in discussion with staff at the centre it appears that there are systems and process in place which provide for the special status of the embryo when carrying out licensed activities.

What the centre could do better.
Nothing noted at the time of inspection.

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.

Prior to storage, providers of gametes and embryos are screened for HIV, Hepatitis B and Hepatitis C (Licence Condition 50 (a)). A checklist is used to ensure screening status is reviewed prior to cryopreservation. A system to separate unscreened and screened material is in place (Licence Condition T50).

Dewars are audited annually and the Embryology Manager described the process undertaken. The most recent audit report from December 2010 and evidence of corrective

action taken were reviewed. .

The centre has a comprehensive bring forward system managed by the embryology manager. She explained that annual invoices sent to patients include a reminder of the expiry date. Contact is then made six months prior to expiry, following which monthly follow up via letter and telephone is undertaken. Data is exported from the centre's database and maintained on a separated spreadsheet. The spreadsheet indicated that all licensed material is currently in storage within the consented storage period, with one exception (detailed below) (add reference).

An audit of 10 patient and donor records confirmed appropriate treatment and storage consents were in place.

What the centre could do better.

One set of embryos is in storage without effective consent, consent having expired on 5 May 2011. This situation arose because the patient had previously indicated, verbally and in writing, an intention to extend storage and in such circumstances staff were reluctant to allow the embryos to perish. The centre was able to produce an audit trail of their contact and attempted contact activity, and the PR confirmed that a final recorded delivery letter and first class letter had been sent on the day of inspection. (T79)

There was no risk assessment available at the time of inspection to support the centre's decision not to conduct HTLV-1 screening prior to storage. (Licence Condition T50(c) T52 (g)).

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*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

Distribution of gametes and embryos (Guidance Note 15)

The centre has processes in place to ensure gametes and embryos are only sent to other licensed centres in conditions that protect the safety and quality of the gametes and embryos. (T105; T106). Critical transport conditions have been defined and there is a comprehensive SOP in place for transporting gametes and embryos. Checklists are used to ensure all samples are suitable for release and correct information is sent with samples prior to transport.

The centre has exported four sperm samples between 18 March 2010 and 5 May 2011 under General Directions.

The centre has imported 70 sperm samples between 18 March 2010 and 5 May 2011 under General Directions. Compliance with Direction 0006 in relation to the import and export of gametes was demonstrated via a review of two sets of import records and one set of export records on the day of inspection against gamete movement forms (Direction 0006).
What the centre could do better. **Distribution of gametes and embryos (Guidance Note 15)** The centre's "Transfer of material" SOP does not document its recall procedure in detail (Licence Condition T33 (b) and Interpretation of Mandatory Requirements 15C).

▶ **Use of embryos for training staff** (Guidance Note 22) – *only applicable for centres which use embryos to train staff*
What the centre does well. The Embryology Manager confirmed on the day of inspection that embryos had not yet been used for training purposes.
What the centre could do better. The centre's laboratory manual (16.2.6) makes reference to using embryos for the development of new techniques or testing of equipment or consumables (Licence Condition T93).

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 wareness and understanding of leal 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.

The sample of patient/partner and donor notes reviewed on the day of inspection were seen to be clear, legible and well organised. Each record reviewed was seen to include appropriate identifying information and a record of the means by which the patient/donor had been identified; the treatment provided; a medical history; welfare of the child assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out (Licence Condition 46)

What the centre could do better.
Nothing noted at the time of inspection.

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

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

What the centre does well.

The PR provided all information as required by the application process prior to inspection (General Direction 0008, paragraphs 2 and 16). All members of staff cooperated fully with the inspection team and all further information requested at the time of inspection was provided in a timely manner.

The PR has fully implemented the recommendations made in the previous inspection reports and there are no outstanding issues from this time.

To determine whether all licensed treatments are reported to the Authority as required by Direction 0005, a sample of licensed treatments undertaken by the centre between 01/04/2010 and 31/03/2011 was reviewed. The sample of 146 (124 IVF + 22 DI) treatments was drawn from the centre's records and was reviewed against an extract of the Authority's statutory register. All treatments in the audit sample were found to be

recorded on the register.

To ascertain the quality of the data submitted by the centre for inclusion on the register, 52 assorted register form submissions during the above sample period were reviewed against source documentation held on patient and donor records and in laboratory records. A small number of minor errors were found.

What the centre could do better.

The average number of days post HFEA invoice date, before payment was received was 32 days during the 2010/2011 financial year. The PR indicated that a temporary finance manager had been in post during this period, but that a permanent team member had been recruited in the month prior to inspection and this should address the timeliness of invoice payment. (T9d)

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclose of information, held on the HFEA Register, for use in research

What the centre does well.

The centre ensures that information about people having treatment, donors and children born as a result of assisted conception is not disclosed unless authorised to do so (Licence ConditionT43)

All staff receive confidentiality training as part of their induction and there is a “Managing patient confidentiality SOP for staff reference (Licence Condition T33b)

Non-unit staff and contractors are required to review and sign a confidentiality agreement, and where access is required to restricted areas these individuals are escorted by unit staff.

The storage of records is secure but currently fragmented across a number of locations. The PR detailed plans to extend the main storage area and install a dedicated file storage system.

A contractor undertakes the archiving and shredding on notes onsite overseen by centre staff.

Access to the units IT system is controlled via the use of usernames, passwords and the granting of defined access privileges (Licence Condition T45).

An audit of six sets of patient records found appropriate HFEA consent to disclosure forms had been completed and retained within each set of patient notes. Additionally, the disclosure consent given by patients and their partners in relation to disclosure of register information to researchers was found to be accurately reflected on the HFEA register.

What the centre could do better. Nothing noted at the time of inspection.

5. Changes / improvements since the previous inspection on 18 March 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Witnessing The centre has an SOP for the disposal of frozen material which meets witnessing requirements but does not document the witnessing requirements when disposing of fresh material not needed for treatment or storage (T71).	The PR should review the SOP to ensure that it includes the procedure staff are to follow when witnessing the disposing of fresh materials as stated in licence condition T71 and recommended under guidance note 18.4(j). Written confirmation to be submitted to the Inspectorate by 1 June 2010	An audit of patient records conducted as part of the inspection confirm witnessing of disposal. The PR had previously submitted evidence in the form of extracts from the SOP and associated documentation to demonstrate that two staff members are required to witness the disposing of all fresh material, when it is not needed for treatment or storage. **No further action is required.**
Witnessing The witnessing SOP is not fully compliant with guidance, in that it does not include the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records.	The PR should review the witnessing SOP to ensure that it meets guidance note 18.4 (j) of the CoP. Written confirmation to be submitted to the Inspectorate by 1 June 2010	The PR has submitted evidence to demonstrate that staff are aware of the need to cross-check at all stages of clinical and laboratory procedures with identifying information in the patient's medical records. **No further action is required.**
Witnessing It was noted that the time of witnessing is not consistently recorded as required by CoP guidance note 18.7 and that the records do not record all the information required to meet licence condition T71, in that the name and status of the individuals performing and witnessing the activity	The PR should ensure that the time of witnessing is recorded in the patients' records, in that the name and status of the individuals performing and witnessing the activity are included on the documentation. Written confirmation to be submitted to the Inspectorate	Refer to page 9 of report. **No further action is required.**

are not included on the documentation.	by 1 June 2010	
QMS Staff were unable to confirm whether quality indicators and objectives relevant to witnessing have been established or provide evidence that demonstrated witnessing audits have been undertaken against compliance with protocols, regulatory requirements or quality indicators, in an independent way, during the last two years, or if findings and corrective actions have been documented	The PR must ensure that audits of all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken against compliance with protocols, regulatory requirements and quality indicators. These must be independently conducted at least every two years. Findings and corrective actions must be documented. Confirmation that quality indicators and objectives relevant to witnessing have been established and an audit plan or schedule as to when these are to be undertaken should be submitted to the Inspectorate by 1 June 2010	Refer to page 11of report. **No further action is required.**
Staff There was no documented evidence presented to demonstrate the assessment of all staff competence in the performance of their designated tasks	At the time of completing the SAQ the PR was aware of this non compliance, and had completed the pre inspection self assessment questionnaire accordingly The PR should ensure that there is evidence is available to demonstrate that all staff have demonstrated competence in the performance of their designated tasks, and/or updated as required, it is documented in the individual staff members training records. A plan showing timelines for completion of assessment of	Refer to page 15 of report. **Further action is required.**

	all staff should be submitted to the Inspectorate by the 27 May 2010	
Consent Although staff are trained and their competency for obtaining consent is assessed, there is no SOP for staff to follow when obtaining consent	At the time of inspection the PR was aware of this non compliance, had completed the pre inspection self assessment questionnaire accordingly, and one was being written. Written confirmation to be submitted to the inspectorate by 30 April 2010	Refer to page 20 of report. **No further action is required.**
Consent The centre's SOP, documents the process to be followed in the event that someone wishes to withdraw consent to the storage or use of gametes and embryos. However it does not state that the request to withdraw consent is required in writing.	The centre should review the SOP to ensure that it states that the request to withdraw consent is required in writing. Written confirmation to be submitted to the inspectorate by 30 June 2010	The centre's "Informed Consent" SOP was reviewed during the inspection. It indicates that withdrawal of consent must be recorded on a signed fully completed HFEA WC form. **No further action is required.**
Multiple Births The centre from time to time performs Gamete Intra Fallopian Transfer (GIFT) and Zygote Intra-Fallopian Transfer (ZIFT), but the multiple birth minimisation strategy does not reference GIFT or ZIFT.	The centre should review the SOP and ensure that it included GIFT and ZIFT. Written confirmation to be submitted to the inspectorate by 30 June 2010	The "Indications for elective single embryo transfer" SOP was reviewed during inspection. It includes references to GIFT and ZIFT. **No further action is required.**
Record keeping and document control At the time of the inspection the centre was not maintaining a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer in the format set	The PR should ensure that a summary log of cases in which multiple embryos have been transferred to patients' who met the criteria for single embryo transfer is maintained in the format set out in Directions 0003. Written confirmation to be	Refer to pages 15 of report. **Further action is required**

out in Directions 0003.	submitted to the inspectorate by 30 April 2010	
Storage of gametes and embryos Cryopreservation dewars are stored over several locations including the en suite to a consulting room and in a room next to the reception area.	In compliance with recommendations in the last report, the PR should undertake an assessment of the risks of the areas where Cryopreservation dewars are stored. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective actions implemented. Written confirmation to be submitted to the inspectorate by 30 June 2010	The PR has submitted evidence in the form of a policy and procedure for safe handling and use of liquid nitrogen and a general risk assessment of the centre carried out on the 6 May 2010. A Control of Substance Hazardous to Health and Safety (COSHH) risk assessment carried out in March 2009 and again in March 2010, summarised the controls that have been put into place and states subject to the controls being applied, employee exposure to liquid nitrogen is adequately controlled. **No further action is required.**
Legal Parenthood The centres patient information leaflet – 'Parental responsibility' did not reflect the new legal parenthood provisions which came into effect on the April 2009	The PR needs to review the centres leaflet to ensure that it reflects the new legal parenthood provisions (T63, T64 & T65). The PR should also assure himself that all staff fully understands the new legal parenthood provisions (T15). Written confirmation to be submitted to the inspectorate by 4 June 2010	The "Legal Parenthood/Parental Responsibility" patient information document was reviewed during the inspection and found to reflect the requirements of Licence Condition T63, T 64 & T65. **No further action is required.**
Counselling The SAQ stated that although the counsellor was not accredited under the British Infertility Counselling Association (BICA), she could provide evidence of working towards accreditation through the	Evidence should be available to demonstrate that the counsellor is currently working towards BICA accreditation and will send a certificate verifying that she is working towards accreditation.	The counsellor provided email evidence that she is in the process of gaining BICA accreditation pending BICA's review of her CPD activity. The counsellor anticipates that she will receive BICA accreditation during July 2011.

BICA accreditation scheme.	Written confirmation that accreditation has been achieved to be submitted to the inspectorate by 30 September 2010	**No further action is required.**
Record keeping and document control Patient records are stored securely but over several locations, including in toilet areas off consulting rooms.	In compliance with recommendations in the last report, the PR should undertake an assessment of the risks of the areas where patients' records are stored and assess whether there are any risks associated with the storage of records in different locations. It is recommended that the PR seeks the advice of appropriately qualified individuals to advise him as to how to minimise the risks. Findings and corrective actions must be documented and corrective actions implemented Written confirmation to be submitted to the inspectorate by 30 June 2010	The PR has submitted evidence of a risk assessment carried out on 6 May 2010, of the areas where patients' records are stored. The risk assessment identified no additional control measures are necessary and the risk rating was graded as 'low' At the time of inspection additional storage space and procurement of a file storage system was being actively investigated. **No further action is required**
Record keeping and document control The SQA states that the centre did not have an SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005	The PR should ensure that there is an SOP in place for submitting data to the HFEA in compliance with the requirements of Directions 0005 Prior to the inspection the inspection team was informed, by registry that in the last year there have been only 3 errors recorded from this centre.	The PR submitted a copy of the centre's SOP for submitting data to the HFEA, in March 2010, in compliance with the requirements of Directions 0005. Via independent audit it was confirmed that that the quality of data submissions to the HFEA register remains high. **No further action is required.**
Record keeping and document control	At the time of completing the	Evidence was provided on

The SAQ states that the centre has not established quality indicators relevant to submission of data to the HFEA or audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years.	SAQ the PR was aware of this non compliance, and had completed the pre inspection SAQ accordingly The PR must ensure that audits of all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are undertaken in compliance with protocols, regulatory requirements and quality indicators. The centre must ensure that these are conducted independently at least every two years. Findings and corrective actions must be documented. An audit plan or schedule should be submitted to the inspectorate by 17 May 2010	inspection that QIs have been established and audits have been conducted and corrective actions implemented **No further action is required.**

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Witnessing and assuring patient and donor identification (GN18) Administrative staff may undertake witnessing duties on occasion, but competence assessments have not been documented for these staff (Licence Condition T15 (a)).	The PR should ensure that all documented competence assessments are in place for all staff that undertake witnessing. 10 August 2011	Witnessing competency tool created for all relevant staff June 2011. All staff to have competency assessed.	Following review of the submitted competency assessment tool and the PR assurance that competency assessment will be documented for all staff undertaking witnessing, the inspectorate consider this to be an adequate response. No further action required.
Traceability (GN19) A spot check of three consumables in use in the laboratory against the centre's IT system record, found one in three to be incorrect. (T99; T100)	The PR should ensure that the centre's audits of traceability include checking of consumables in use in the lab to the centre's IT system record. An audit should be performed	Traceability audit tool revised June 2011. Traceability audit to be undertaken on consumables and repeated weekly until fully compliant.	Following review of the traceability audit tool submitted by the PR, the inspectorate consider this to be an adequate response. No further action required.

	and the results submitted to the Executive. 10 August 2011		
Validation (GN15) Critical procurement and processing procedures have not been validated(T72)	The PR should submit an action plan, including a summary of all procedures that require validation and timeframes for completion. For submission by 10 August 2011. The PR should submit quarterly reports to the Executive regarding progress of implementation process validation until complete. For full completion by 10 November 2011.	Acknowledged and additional Embryology staff retained for continued process validation and ongoing rolling audit evaluation. Summary of Procedures that require validation to be developed by laboratory manager, Quality manager and submitted to PR by 9th August for forwarding to HFEA by 10th August 2011.	To be monitored as part of the compliance monitoring process. Further action is required.
Equipment and materials (GN26) Heated stages and transport incubators are serviced and temperature mapped on an annual basis, (T24)	The PR should review the appropriateness of the current frequency of critical parameter monitoring of laboratory equipment and inform the Executive. 10 August 2011	All critical equipment included in audit tool including mini transport incubators.	Following review of the audit tool submitted by the PR the inspectorate consider this to be an adequate response. No further action is required.

Premises suitability and air quality (GN25) The centre conducts diagnostic semen assessment, but the laboratory does not have CPA accreditation. T21	The PR should ensure that diagnostic semen assessment is conducted in a laboratory with CPA accreditation. To be progressed as quickly as possible. PR should submit a plan to the Executive documenting the estimated timeline for achieving compliance. 10 August 2011.	We understood that the word equivalent allowed UK NEQAS who are our Quality Assurance assessors to suffice this requirement. Application to CPA for Andrology testing to be submitted. We require approval by Nuffield Health main board for costs involved and are therefore exploring possibility of submitting application via Nuffield Health's corporate CPA accreditation. We note HFEA statement only released 30th June 2011 re T21 and will not be able to achieve accreditation by 10th August 2011.	The executive has noted the PR comments. Progress to be monitored as part of the compliance monitoring process. Further action is required.
Third party agreements (GN24) There was no TPA in place with a courier company used by the centre to distribute gametes. (T111)	The PR should ensure that a third party agreement is put in place with the courier company used to distribute gametes. 01 November 2011	Third party agreement forms sent to courier and waiting for a reply.	To be monitored as part of the compliance monitoring process. Further action is required.

Storage of Gametes and embryos (GN17) At the time of inspection, one set of embryos were being stored without valid consent.	The PR must take appropriate action regarding the continued storage of these embryos and inform the Executive of the action taken immediately.	All stored material has valid consent. Laboratory SOP 20.1 revised to cover new process. A new pt non-response – disposal of cryostored sperm/embryo checklist implemented in which tick boxes have to be signed and witnessed at each stage of action taken.	The executive notes the action taken by the PR. No further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Multiple Births (GN7) A log recording elective multiple embryo transfers by patients is not maintained in the form prescribed by Direction 0003.	The PR should ensure that the a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer is kept as set out in the centre's multiple birth strategy. 10 November 2011	Summary log created.	Following review of the eSET summary log submitted by the PR the inspectorate consider this to be an adequate response. No further action is required.
Legal parenthood (GN3) At the time of inspection there were no documented legal parenthood procedures available for staff reference. (T33b)	The PR should ensure there are written procedures for staff to follow and refer to in relation to legal parenthood. 10 August 2011	SOP/Nursing General Protocol no 15 – Informed consent revised to cover Legal parent/parental responsibility.	Following review of the revised SOP submitted by the PR the inspectorate consider this to be an adequate response. No further action is required.
Storage of Gametes and embryos (GN17) HTLV-1 testing is not performed prior to storage of patient gametes/embryos (Licence Condition T50C)	The HFEA has recently sought and obtained expert opinion on HTLV-1 screening and have released sector guidance. The PR should conduct a risk assessment to determine the requirement for HTLV-1 testing	We understand there is ongoing negotiation between the British Fertility Society and the HFEA. Risk assessment to be completed by 10/11/11	The PR's response is noted. To be monitored as part of the compliance monitoring process. Further action is required.

	prior to storage.		
Use of embryos for training staff (GN22) At the time of inspection the Embryology Manager confirmed that embryos had not been used training purposes. The centre's Laboratory Manual makes reference to using embryos for development of new techniques or testing of equipment or consumables, unlike training of staff the above are not authorised uses. (Licence Condition T93)	The PR should ensure the Laboratory Manual is revised to reflect authorised uses of embryos only. 10 August 2011	Laboratory SOP 16.2.7 changed.	Following review of the revised laboratory SOP submitted by the PR the inspectorate consider this to be an adequate response. No further action is required.
Legal requirements GN 30) The average number of days before payment of HFEA invoice during the 2010/2011 financial year was 32 days. (Licence Condition T9(d))	The PR should ensure that payment of HFEA invoices is made within 28 days of the invoice date. Immediately.	Licence Holder discussed with Nuffield Health Finance Manager requesting to arrange a system review.	The executive notes the action taken by the PR. To be monitored as part of the compliance monitoring process. Further action is required.
Recall Procedures (GN15) The Embryology Manager outlines a comprehensive recall procedure, but this procedures was not	The PR should ensure that the centre's recall procedure is documented and available for staff reference.	Laboratory SOP 19.6.3 changed	Following review of the revised laboratory SOP submitted by the PR the inspectorate consider this to be an adequate response.

documented at the time of inspection. (Directive 2006/86/EC)	10 August 2011		No further action is required.
Traceability (GN19) The centre's traceability SOP does not include the requirement that all equipment used is recorded. Nevertheless, review of traceability records during inspection found that equipment used is recorded in practice. (T33b)	The PR should ensure that the traceability SOP is revised to include the requirement that all equipment used is recorded. 10 August 2011	Laboratory SOP 20.8 changed	Following review of the revised laboratory SOP submitted by the PR the inspectorate consider this to be an adequate response. No further action is required.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

21 July 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0144 (The Woking Nuffield Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance and Facilities Ian Peacock, Analyst Programmer	Lauren Crawford

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 is located in the Assisted Conception Unit at Nuffield Health, Woking Hospital, Surrey and provides treatments to both NHS and self-funding patients.

2. The Panel noted that the centre offers a wide range of treatments including ovulation induction, in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). The Panel also noted the centre conducts approximately 1400 treatment cycles per year.

3. The Panel noted that the centre's success rates for IVF/ICSI is in line with the national average with the following exceptions:

    - ICSI cycles using fresh embryos created from patients' eggs for the 16-37 age group are above the national average; and
    - FET (Frozen Embryo Transfer) cycles for the 16-39 age group are below the national average.

4. The Panel noted the centre's multiple birth rate for 2009 was 20.1% with an elective single embryo transfer rate of 8.3% for the same period. This is significantly below the 2008/2009 multiple pregnancy rate target of 30%.

5. The Panel noted that, at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including seven major areas of non-compliance and seven other areas of non-compliance or poor practice.

6. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence to the Inspectorate that four major and three other areas of non-compliance have been fully implemented.

7. The Panel noted that one of the major areas of non-compliance referred to a single set of embryos being stored without valid consent. The Panel also noted that the PR had taken appropriate action to rectify this.

8. The Panel noted the centre has been pro-active in regards to recommendations from the previous inspection report. All such areas of non-compliance were fully implemented. The Panel also noted the centre has developed a number of SOP's.

9. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

The Panel's Decision

10. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

11. 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 HF&E Act 1990 (as amended).

12. 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.

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

14. The Panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [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.

15. The Panel considered it had no concerns in the matters specified as the centre and PR had either already addressed or committed to resolve the areas identified in the report.

16. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions and endorsed the Inspectorate's recommendations in the report.

17. The Panel urged the PR to complete the outstanding recommendations, within the agreed timeframes.

Signed Peter Thompson Date 3/8/11.

Peter Thompson (Chair)