Renewal Inspection Report

Date of Inspection: 20 October 2010
Length of inspection: 8 hours
Inspectors Sara Parlett (HFEA; Lead Inspector)
Paula Nolan (HFEA; Clinical Inspector)
Jason Kasraie (External; Scientific Inspector)
Chris Hall (HFEA; Operational Audit)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received about the centre between 15 September 2010 and 14 January 2011.

Date of Executive Licensing Panel: 14 January 2011

Purpose of the Inspection report
The purpose of the inspection is to assess if centres are complying with the HF&E Act 1990 (as amended), the 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	NURTURE
Centre Number	0076
Licence Number	L0076-13-c
Centre Address	'B' Floor, East Block University Hospital Nottingham NG7 2UH
Telephone Number	0115 8230700
Person Responsible	Mr James Hopkisson
Licence Holder	Professor James Thornton
Date Licence Issued	5 July 2007

Licence expiry date	31 May 2011
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

NURTURE has been licensed by the HFEA since 1992 and offers a comprehensive range of licensed treatments to both self funding and NHS contracted patients from Nottingham and surrounding counties.

The centre is located within the campus of Queens Medical Centre which is part of Nottingham University NHS Trust. NURTURE is owned by the University of Nottingham and has been registered with the Care Quality Commission since 2005.

The centre is considered to be moderate in size, offering approximately 550-600 licensed treatment cycles per year.

The Person Responsible (PR), Mr James Hopkisson, is a sub specialist in Reproductive Medicine and has been on the speciality register of the General Medical Council for Reproductive Medicine, Obstetrics and Gynaecology since 2002. Mr Hopkisson is the Medical Director of NURTURE and has satisfactorily completed the PR entry programme. He has held the post of PR since 2003.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01/06/2009-31/05/2010*
In vitro fertilisation (IVF)	263
Intracytoplasmic sperm injection (ICSI)	246
Frozen embryo transfer (FET)	68
Donor insemination (DI)	0
Intra uterine insemination (IUI) (Data from 01/01/09 – 31/12/09)	16

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

*These data were extracted from the HFEA register for the period 01/06/09-31/05/10. 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 Inspectorate considers that there is 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 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 Directions 0008, in application for renewal of their licence.
- The centre has submitted an application fee to the HFEA in accordance with requirements.

Recommendation to the Executive Licensing Panel:

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 five major areas of non-compliance and eight other areas of non-compliance.

Since the inspection visit on 20 October 2010 the PR has provided evidence that, in the view of the inspection team, provides sufficient information to conclude that the centre is now compliant with the following recommendations.

Major areas of concern:

- To establish quality indicators for donor recruitment and selection processes.
- To revise the centre's "Information and consent" standard operating procedure (SOP) to detail the processes to follow when providing information prior to consenting patients and the process to follow when obtaining consent.

Other areas of concern:

- To ensure that all containers used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's **full** name and unique identifier.
- To ensure that the centre's adverse incident policy specifies the timeframe for reporting incidents to the HFEA.
- To revise the centre's "Donor schemes" SOP detailing the information to give to patients to clarify the information that can be obtained by donor conceived children and the point at which donors may vary or withdraw their consent.
- To develop an SOP for the procedure to be followed for withdrawal of consent to being the legal parent.
- To establish an SOP for the control of access to health data and records, to cover all requirements of Licence Condition T44.

The Inspection team recommends that the Executive Licensing Panel is asked to require that the PR complies with the following recommendations within the prescribed timeframes set out in the inspection report:

Major areas of concern:

- To ensure that CE marked medical devices are used, wherever possible.
- To ensure that the processes undertaken to submit data to the Authority are reviewed and revised to ensure compliance with the reporting periods stipulated within Directions 0005.
- To assure the accuracy of data provided via the Electronic Data Interchange (EDI) system regarding consent to the disclosure of identifying information to researchers.

Other areas of concern:

- To carry out audits of counselling activities against compliance with the approved protocols.
- To ensure that the third party agreement with a courier company for the transport of gametes and embryos defines the critical transport conditions and the requirement for maintenance of those conditions.
- To ensure that nursing and counselling staff can provide documented evidence of the assessment of their competence in all designated tasks.

The Inspection team considers that, overall, there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions.

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of treatment**

- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services

- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)

- **Ensuring donor gametes are only used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas:
    - Witnessing

- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre:
    - Establishment of quality indicators for and audit 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, against compliance with the approved protocols, the regulatory requirements and quality indicators.
    - Demonstrated evidence of the assessment of competence of relevant staff to provide counselling.
    - Defined critical transport conditions, to ensure that the required tissue and cell properties and viability are maintained.
    - Monitoring of equipment or materials that affect critical processing or storage parameters.

Take account of 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 (Principle 4).

What the centre does well.

Welfare of the child: Guidance Note 8

Centre staff provided verbal and written evidence that before a woman is provided with treatment services, account is taken of the welfare of any child who may be born as a result of the treatment and of any other child who may be affected by the birth (Licence Condition T56). The centre has a welfare of the child (WoC) assessment SOP (Licence Condition T33 (b)) which documents the criteria for re-assessment of patients (CoP guidance 8.6). The nurse manager confirmed that in the case of surrogacy, both those commissioning the arrangement and the surrogate and surrogate's partner are assessed (CoP guidance 8.4).

Quality indicators have been established (Licence Condition T35) and an audit by the centre in May 2010 found that not all WoC assessments were completed (Licence Condition T36). Corrective action was seen to be taken and in the three sets of patient records audited on inspection all were found to include completed WoC assessments for each patient.

What they could do better.

Nothing noted at the time of inspection.

Conduct 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 (Principle 7).

What the centre does well.

Good clinical practice: Guidance Note 15

All critical procedures conducted at the centre are documented in SOPs, a sample of which was reviewed and found to be comprehensive (Licence Condition T33 (b)). All critical processes have been identified and validated in compliance with Licence Condition T72. A selection of validation documents were reviewed at inspection, including ICSI and storage procedures.

Quality indicators relevant to procurement and processing procedures are monitored and include fertilisation rate, ICSI damage rate and clinical pregnancy rate per embryo transfer (Licence Condition T35). Thresholds have been set, under which level corrective action is taken (Licence Condition T36).

The quality management system: Guidance Note 23

The centre has a comprehensive quality management system (Licence Condition T32) and documentation was seen to include a quality manual (Licence Condition T33 (a)), a quality policy (CoP guidance 23.3 (b)) and quality objectives (CoP guidance 23.9). The quality manager confirmed that the centre has applied for recertification to ISO 9001:2008 and a pre-registration visit is organised for November 2010.

Reviews of the quality management system were held in February and October 2010 and included a review of centre resource requirements and staff training needs (CoP guidance 23.12).

Quality indicators have been established, with one exception (detailed below) (Licence Condition T35). The centre's internal audit plan for 2010 details audits conducted, along with the completion of any corrective actions, and audits scheduled for completion. A sample of audits performed was reviewed, including audits of patient consents, donor selection procedures and laboratory procedures. Rolling audits for traceability and witnessing are performed at the centre. The senior embryologist explained that all patient records are reviewed at the end of each treatment cycle to ensure all witnessing and traceability records are complete (Licence Condition T36).

The centre has a document control policy to ensure that only current versions of documents are in use (Licence Condition T34). The policy states that all documents are to be reviewed annually and all documents seen at inspection had been reviewed within the last year (CoP guidance 31.6). The quality manager explained that a new database had recently been installed and would be used for the management of centre documents, incidents and complaints.

The centre's last user satisfaction survey was performed two years ago. The quality manager confirmed that they are in the process of modifying the survey, which will then be managed through a third party (CoP guidance 23.17). A staff satisfaction survey was conducted in September 2010 and the results are currently being analysed (CoP guidance 23.18).

Diagnosis and investigation of patients, donors, gametes and embryos: Guidance Note 25.

It was confirmed at inspection that the laboratories undertaking diagnosis and investigation of patients and donors are accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (Licence Condition T21).

Donor recruitment, assessment and screening: Guidance Note 11

The centre has an active egg share programme coordinated by the nurse manager. Nursing checklists were reviewed at inspection and are used to ensure all relevant patient information is given and screening is completed prior to patients starting treatment.

The centre's donor assessment and screening procedures are supported by a SOP that is compliant with Licence Condition T52. Three sets of medical records pertaining to egg donors were audited during the course of the inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal interview and physical examination performed by a qualified and trained medical professional (Licence Condition T52 (a)).
- Donors are being selected in accordance with the screening requirements of Licence Condition T52 and relevant professional bodies[1].
- The laboratory tests required by Licence Condition T52 have been carried out by a qualified laboratory which has been accredited by CPA (UK) Ltd (Licence Condition

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

T53 (a)).

Surrogacy: Guidance Note 14

The centre offers surrogacy treatment, and on average performs two to three cycles per year. The nurse manager confirmed that patients are treated in the same way as other donors, including the requirement for quarantining donor sperm (Licence Condition T53 (c)).

What they could do better.

The quality management system: Guidance Note 23

The centre has not established quality indicators for the recruitment and selection of donors (Licence Condition T35).

The counsellor stated that audits of counselling activities against compliance with the approved protocols have not been carried out (Licence Condition T36).

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

What the centre does well.

Premises and facilities: Guidance Note 25

The activities authorised by the centre's licence are carried out at the premises specified in the licence (Licence Condition T1). A copy of the certificate of licence is displayed in the patient waiting area (Licence Condition T5).

Particle counts in all critical working areas and the background environment are monitored on a monthly basis and records show that the air quality is compliant with the requirements of Licence Condition T20.

Cleaning of the premises is conducted, including weekly deep cleaning of the laboratories (Licence Condition T26).

Equipment and materials: Guidance Note 26

Laboratory staff provided documented evidence of regular cleaning of equipment and that all equipment that effects critical processing or storage parameters are subject to monitoring, alerts and alarms (Licence Condition T24). The centre has an on call rota and a comprehensive SOP for responding to incubator and dewar alarms out of hours.

The centre maintains a spreadsheet recording the details of servicing of critical equipment, which showed that all equipment had been serviced in 2010 (Licence Condition T24).

Critical equipment has been validated and validation records for one incubator were reviewed (Licence Condition T24). Records of revalidation of another incubator after repair were also seen (Licence Condition T25). It was observed that equipment with critical measuring functions are calibrated against traceable standards (Licence Condition T24).

The centre has SOPs documenting the procedures for operating critical equipment, and a sample was reviewed. An SOP was seen to document the action to be taken in the event of malfunction or failure of equipment (Licence Condition T27).

Witnessing and assuring patient and donor identification: Guidance Note 18

The centre has documented SOPs describing the procedure to be followed for the witnessing of all critical points of the clinical and laboratory processes (Licence Condition T70). Witnessing was observed during the inspection and was in accordance with centre protocols.

Four sets of patients notes audited at inspection were found to include records of all required witnessing steps, including the date and time of the witnessing (Licence Condition T70).

Evidence of competence assessments of staff performing witnessing steps was reviewed (Licence Condition T15 (a)).

Storage of gametes and embryos: Guidance Note 17

Centre staff confirmed that eggs are not currently frozen at the centre. The cryoroom containing dewars of stored sperm and embryos was seen to be secure and the dewars alarmed (CoP guidance 17.5). Prior to storage the providers of gametes and embryos are screened for HIV, Hepatitis B and Hepatitis C (Licence Condition T50 (a)) and a checklist is used to ensure that screening status is reviewed prior to cryopreservation. A system to separate unscreened, screened and known positive samples is in place (Licence Condition T50 (b)).

The centre's "Cryopreservation and storage" SOP details the controlled conditions for the slow freezing and vitrification of embryos and freezing of sperm (Licence Condition T75).

Traceability: Guidance Note 19

The centre's "Quality assurance and quality control" SOP, describing the requirement for the traceability of consumables, reagents and equipment was submitted prior to inspection (Licence Condition T33 (b)). Records reviewed at inspection indicated that all gametes and embryos and all relevant data relating to anything coming into contact with those gametes or embryos are traceable (Licence Condition T99), including identification of critical equipment used. This data was seen to be kept for the required length of time (Licence Condition T103).

Transport of gametes and embryos: Guidance Note 15

The centre's "Transfer of material to and from NURTURE" SOP describes the requirements for the receipt of gametes and embryos at the centre (Licence Condition T109 and T110) and for the packaging and transport of material. The senior embryologist confirmed that the dry shipper is monitored regularly for temperature and time limits for use (Licence Condition T106). A template label for transport was seen to be compliant with Licence Condition T107.

The senior embryologist confirmed that the requirements of Directions 0006 are complied with for the import and export of material. The centre has a checklist for the assessment of the suitability for import of donor sperm from another EEA state prior to transport, which includes all requirements of Directions 0006.

Evidence was provided that embryo and gamete movement in and out forms are submitted to the HFEA as required (Directions 0005).

Third party agreements: Guidance Note 24

The centre has written agreements with third parties providing goods and services

influencing the quality and safety of gametes and embryos and a list of these agreements was seen (Licence Conditions T111 and T115). A sample of agreements were reviewed and found to be compliant with Licence Condition T114 with one exception, detailed below.

What they could do better.

Equipment and materials: Guidance Note 26

Not all consumables used in the laboratory are CE marked, where suitable CE marked consumables are available (non compliant with Licence Condition T30). The senior embryologist explained that where CE marked devices are not used, validation has been carried out, including in house sperm toxicity assays for each batch of new consumables. Although the Inspectorate is satisfied that steps have been taken to mitigate the risks of using non CE marked devices, the Inspectorate remains concerned that potentially embryo toxic material could be missed by the in house quality testing procedures.

Witnessing and assuring patient and donor identification: Guidance Note 18

Some samples of gametes and embryos are labelled with only the patient's surname and unique identifier. Licence Condition T101 requires that all containers used are labelled with the patient's full name.

Third party agreements: Guidance Note 24

The centre has a third party agreement with a courier company for the transportation of gametes and embryos. The third party agreement does not define the critical transport conditions nor has the requirement for the maintenance of those conditions been documented (Licence Condition T114 (e)).

▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).

What the centre does well.

Staff: Guidance Note 2

An organisation chart defining accountability and reporting relationships for the centre was seen to be appropriate (Licence Condition T11). The quality manager confirmed that the staff recruitment process is handled by the University's Human Resource Department, and includes uptake of references and criminal records bureau (CRB) checks for all members of staff (HFE Act 1990 (as amended), Section 17 (1) (a)).

The centre has a SOP describing the induction and competence assessment requirements of staff, including reassessment after absence. The quality manager confirmed that the centre intends to reassess staff competencies every two years (Licence Condition T12). Templates for the induction of staff from all disciplines were seen, and records were seen for a selection of staff, including the training of administration staff in confidentiality requirements. One new nurse interviewed at inspection described a highly supportive induction period, where the first month involved solely shadowing various members of staff and patient procedures.

All nursing staff have had an appraisal and had their training needs identified. Basic competencies, including provision of information to patients and obtaining consent have been assessed. The nurse manager is now in the process of expanding the competencies using the Nursing and Midwifery Council (NMC) Fertility Nurses competence framework.

Records of competence assessments of laboratory staff were reviewed at inspection and considered comprehensive and included training in the use of critical equipment.

Mandatory training, including health and safety, fire and resuscitation, is managed using a dedicated database seen at inspection. The quality manager confirmed that appraisals are conducted annually and records are maintained (CoP guidance 2.1 (c)).

It appeared at the time of inspection that personnel are available in sufficient number for the present activity and workload (Licence Condition T12).

All staff, where appropriate, were seen to be registered in accordance with the relevant professional and/or statutory bodies (Licence Condition T14).

Staff training and continual professional development needs were seen to be reviewed at the centre's October 2010 management review, and resources allocated for training provision (Licence Condition T15).

What they could do better.

Staff: Guidance Note 2

Nursing staff could not provide documented evidence of the assessment of their competence in all designated tasks (Licence Condition T15 (a)). Further progress is required to ensure the nursing competence framework is reflective of current nursing duties, including clinical procedures.

One counsellor interviewed at inspection provided evidence of training and continued professional development. A competence framework template was provided by the centre, but has not yet been initiated (Licence Condition T15 (a)).

▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).

What the centre does well.

Adverse incidents: Guidance Note 27

The centre has reported adverse incidents to the HFEA since the last inspection. All reporting has been performed in a timely manner in compliance with Licence Conditions T120 and T121 and Directions 0011.

The centre's non-conformance log was reviewed at inspection and indicated that reportable incidents that occurred within the last year had been reported to the HFEA.

Complaints: Guidance Note 28

The centre has a complaints policy that was reviewed at inspection and a complaints information notice is displayed in the waiting area (CoP guidance 28.5). A log of all complaints is maintained and evidence was seen that complaints are responded to within the required timeframe.

What they could do better.

Adverse incidents: Guidance Note 27

Although incidents have been reported to the HFEA in a timely manner, the centre's adverse incident policy does not specify that incidents should be reported within 24 hours

(Directions 0011, Licence Condition T33 (b)).

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas:
    - Information about the cost of treatment (costed treatment plans)
    - Legal parenthood

- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre:
    - SOP for taking effective consent.
    - SOP to ensure that all information is kept confidential and only disclosed in circumstances permitted by law.
    - SOP for the control of access to health data and records.

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
What the centre does well. **Treating people fairly: Guidance Note 29** Evidence was provided at inspection that all patients and donors are provided with treatment carried out at suitable licensed premises. The centre has a SOP stating that it is policy to perform all activities in a non discriminatory way, and with respect for the privacy and dignity of all patients and staff. Centre staff have attended equality and diversity training courses. The centre's "Protecting dignity and privacy" SOP states that a member of staff with a true conscientious objection to participating in an activity does not have to do so (HFE Act 1990 (as amended) Section 38(1)).
What they could do better.

Nothing noted at the time of inspection.

▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).

What the centre does well.

Counselling: Guidance Note 3

The centre employs two counsellors and the counsellor interviewed at inspection reported that she was well supported in her role by other centre staff. The counsellor interviewed holds a recognised counselling qualification and is currently working towards accreditation by the British Infertility Counselling Association (CoP guidance 2.12).

The availability of counselling is described in the initial information pack sent to patients (Licence Condition T58 (f)) and a comprehensive selection of counselling patient information is available and on display in the waiting area.

Counselling SOPs are in place (Licence Condition T33 (b)), regular audits of the counselling service are carried out and an audit performed in January – February 2010 was reviewed at inspection. A counselling patient information survey was conducted between May and November 2009 and positive responses were received.

Confidentiality: Guidance Note 30

A tour of the centre confirmed that patient records are stored securely. The centre has a "Protecting confidentiality" SOP, to ensure patient information is kept confidential and that people accessing identifying information are aware of relevant legislation (Licence Condition T43). Confidentiality agreements are signed by all persons accessing the premises and patient information and evidence of this was seen in staff training files.

Comfort and privacy: Guidance Note 25

A tour of the centre confirmed that patients are provided with an acceptable level of privacy and comfort. All treatment, scanning, consultation and counselling rooms appeared to be suitable for the purpose for which they are used including confidential discussions and personal physical examination and treatment (Licence Condition T9 (b)).

What they could do better.

Nothing noted at the time of inspection.

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).

What the centre does well.

Information to be provided prior to consent: Guidance Note 4

The centre submitted a suite of patient information prior to inspection, covering the majority of the requirements of the Code of Practice. Information not provided in leaflets is provided verbally during the clinical assessment appointment (including information regarding the potential risks of fertility treatment in general and the risks of ICSI) (CoP guidance 4.2 (f)

and 21.1). A selection of patient information leaflets is on display in the patient waiting area.

Patients are provided with a costed treatment plan prior to treatment. A copy is kept in the patient notes and a copy given to the patient. Information and charges regarding storage costs are included (CoP guidance 4.3).

Donor assisted conception: Guidance Note 20

The centre's "Donor schemes" SOP states that it is mandatory for patients having treatment with donor gametes to undergo counselling prior to treatment. Patient information leaflets as well as discussions with nursing and counselling staff highlights the importance of informing children of their donor origins (HFE Act (1990) as amended, section 13 (6c)).

The centre maintains detailed records and can provide donors with information regarding the number, sex and year of birth of persons born as a result of donation (HFE Act 1990 (as amended), Schedule 31ZD (3)).

An audit of the registration status of sperm donors used at the centre was performed in August 2010 and showed full compliance with Licence Condition T54.

It was confirmed that treatment services are provided to the egg sharers in the course of the donation cycle (Directions 0001, paragraph 6).

Legal parenthood: Guidance Note 6

Staff have received training in the legal parenthood provisions and training certificates were seen in the nurse training files (Licence Condition T15 (a)). Information regarding legal parenthood provisions is provided in patient information leaflets. The counsellor interviewed confirmed that legal parenthood is also discussed as part of the patient's implications counselling (Licence Condition T60 and T61).

What they could do better.

Donor assisted conception: Guidance Note 20

The patient information section of the centre's "Donor schemes" SOP states that "presently the law does not allow the children who may apply for information from the HFEA register to know the identity of the donor". It does not clarify the information that can be obtained at 16 (HFE Act 1990 (as amended), sections 31ZA and 31ZB) and the identifying information that can be accessed at 18 years of age (HFEA (Disclosure of Donor Information) Regulations 2004). The SOP also states staff must explain to the donor that they "may change their mind at any time". CoP Interpretation of mandatory requirements 5H states that consent can be varied or withdrawn at any point until the gametes or embryos are used to provide treatment services.

Legal parenthood: Guidance Note 6

The centre does not have a SOP documenting the procedure to be followed for withdrawal of consent to being the legal parent (Licence Condition T33 (b)).

▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).

What the centre does well.

Consent to treatment, storage, donation, and disclosure of information: Guidance Note 5

Centre staff provided evidence that written consent is obtained from patients prior to treatment (Licence Condition T57). Four sets of patient notes were examined during the

inspection and found to contain effective consent, including consent for the disclosure of information to researchers.

The senior embryologist demonstrated the bring forward system used at the centre for the management of stored gametes and embryos. Contact is initiated with patients six months prior to the expiry of the consented period (CoP guidance 17.17). The system is managed by a trainee embryologist under the supervision of the senior embryologist. The centre's embryo database showed that all embryos in storage were within their consented storage period (Licence Condition T79).

The senior embryologist explained that during the laboratory pre-freeze checking procedure, staff confirm that consents to storage are present and completed appropriately.

The centre's "Cryopreservation and storage" SOP includes a description of the cooling off period (HFE Act 1990 (as amended), Schedule3, paragraph 4A (4)). The senior embryologist confirmed that the cooling off period had been used by the centre, but that the embryos had since reached the statutory storage period and had been disposed of.

What they could do better.

Consent to treatment, storage, donation, and disclosure of information: Guidance Note 5

The centre has an "Information and consent" SOP, but this does not describe in detail the process to follow when providing information prior to consenting patients or the process to follow when obtaining consent. The Inspectorate considered that the SOP would not effectively support a new member of staff in ensuring the correct consent forms for particular treatment scenarios are completed by patients.

Live Birth Rates

Relative live birth success rates from the HFEA held register data from 01 January 2007 to 31 December 2009 show:

The centre's success rates are in line with the national averages with the exception that IVF/ICSI treatments for the below 35 age group is significantly above the national average.

Multiple Births

What the centre does well.

Data extracted from the HFEA register for 2008 and 2009 show multiple clinical pregnancy rates of 27.8% and 37.1% respectively.

The centre has since achieved a significant decrease in its multiple clinical pregnancy rate. The PR reported an overall multiple clinical pregnancy rate at the time of inspection of 21% over the last six months. This is supported by data received and analysed from the HFEA Register.

In compliance with Directions 0003, the centre has a documented record of their multiple birth minimisation strategy (MBMS) including:

- How the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria (Directions 0003 (5(a)).
- How the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (Directions 0003 5 (b)).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the

strategy (Directions 0003(c)). Where more than one embryo has been transferred, the centre has recorded in the patients' records an explanation of the reasons for transferring more than one embryo in that particular case. Thirty two patients have had two embryos transferred in 2010, the PR confirmed that this was due to patient demand and that all had signed a disclaimer, confirming that information regarding risks had been given and that they wished to have two embryos transferred against the centre's recommendation, copies of this disclaimer were seen in the patient notes.

The PR stated that three embryos have not been transferred to any patients in the last year. This was confirmed by reviewing the centres three embryo transfer log.

The centre's "benefits of single embryo transfer" patient information leaflet was reviewed and includes details of the risks of multiple pregnancy (CoP guidance 7.6). The PR confirmed that multiple birth risks are also discussed at the patient information evening.

The PR confirmed that the centre continuously reviews the progress of its strategy by keeping a running total of multiple pregnancies. The PR agreed to summarise the results of the rolling audit to submit as required for the renewal application.

What the centre could do better.

Nothing noted at the time of inspection.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre:
    - There were no areas of concern identified prior to the on site inspection.

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).
What the centre does well. **Patient selection: Guidance Note 15** Justification for the use of gametes and embryos in treatment, based on the patient's medical history and therapeutic indications was seen documented in patient notes reviewed at inspection (Licence Condition T49). **Payment for donors: Guidance Note 13** The centre does not recruit sperm donors. However, the centre does run an egg share program and this service in compliant with Directions 0001.
What they could do better. Nothing noted at the time of inspection.

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).
What the centre does well. **Storage of gametes and embryos: Guidance Note 17** The senior embryologist stated that all dewars are audited on an annual basis and described a comprehensive procedure for the audit, including cross referencing to the consent for storage in the patient records. The audit report from October 2010 was reviewed and showed that only minor data entry discrepancies were found (CoP guidance 17.16). The senior embryologist explained that the centre has an ongoing plan to replace all dewars and are purchasing two new dewars annually. The senior embryologist confirmed that liquid nitrogen levels are physically checked on a weekly basis, and dewar alarms are checked monthly (Licence Condition T24). **Use of embryos for training staff: Guidance Note 22** The senior embryologist confirmed that embryos are not currently used for the purpose of training staff at the centre.
What they could do better. Nothing noted at the time of inspection.

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**
- **Inspection theme 2010 - 2012** – for this period, this should include the following:
- Patient consent to the disclosure of information, held on the HFEA register, for use in research
- Consent issues in relation to the storage of embryos (including cooling off period)
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked at during the inspection visit to this centre:
    - Submission of data to the HFEA.

▶ Maintain accurate records and information about all licensed activities (Principle 10).
What the centre does well. **Record keeping and document control: Guidance Note 31** All patient records sampled during the inspection were seen to be well organised and in good order, with appropriate document control.
What they could do better. **Record keeping and document control: Guidance Note 31** The centre does not have a SOP in place for the control of access to health data and records (non compliant with Licence Condition T44).

▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or 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-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).
What the centre does well. All members of staff cooperated fully with the inspection team and information requested prior to and at the time of inspection was provided in a timely manner. To date, in this financial year, the centre has taken an average of 42 days to pay HFEA invoices. However, their last three invoices have been paid within 28 days, as required by

Licence Condition T9 (d).

What they could do better.

Obligations and reporting requirements of centres: Guidance Note 32

Not all errors identified after the EDI forms are submitted to the Authority are cleared within the two calendar month period required by Directions 0005. It was confirmed that centre staff are working to reduce the number of error reports and the PR stated that the introduction of a new database would improve this.

Licensed Treatment Reporting

To determine whether all licensed treatments are reported to the Authority as required by Directions 0005, a sample of licensed treatments undertaken by the centre between 01/09/09 and 31/08/10 was reviewed.

A sample of 134 treatments made up of 133 IVF and 1 DI treatment was taken. Ten (8%) IVF and one DI treatment in the audit sample were found to be unreported at the time of inspection.

Only seven (6%) of the 134 treatment cycles in the audit sample were reported to the HFEA within 5 working days of treatment as required by Direction 0005.

To ascertain the quality of the data submitted by the Centre for inclusion on the statutory register, 54 sets of assorted form data submitted to the Authority between 01/09/09 and 31/08/10 was reviewed against source documentation held on patient and donor files. 23 (43%) contained error or omission. No errors were found in critical fields (e.g. a donor reference) that could affect the Authority's ability to fulfil obligations to offspring.

Consent to the use of information held on the HFEA Register for use in research

The bulk of the errors found, referred to above, related either to discrepancies between patient and partner consent to the disclosure of register information for research purposes, or the lack of evidence to support the disclosure consent recorded by the centre on patient and partner registration forms submitted to the Authority.

With regard to consent to the disclosure of register information for research purposes, there were a number of instances of the old consent to disclosure forms being used that do not include the consent to the use of register data questions, though consent has been recorded as being provided on the registration form submitted to the HFEA. In five instances the register submission indicates the patient and/or partner have given consent to being contacted in relation to the above, even though there is no supporting evidence to this effect on file. The above stems from disclosure consent forms completed pre 1 October 2010 and which do not include the register data research questions, being used to support patient registrations post 1 October 2009.

5. Changes / improvements since the last inspection on 3 December 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Appropriate information should be provided regarding the implications of consent to parenthood. Licence Condition T58.	The PR should ensure appropriate information is provided.	The centre provided evidence of staff training in the provision of information regarding legal parenthood and information is provided in patient information leaflets. **No further action required.**
Appropriate consent to parenthood should be obtained before donor sperm is inseminated or before embryos created using donor sperm are transferred. HFE Act 2008, part 2, sections 36 & 37.	The PR should ensure appropriate consent is obtained.	The centre provided evidence of staff training in the use of consent forms for legal parenthood. The centre has an "Information and consent" SOP, but the Inspectorate considered that the SOP would not effectively support a new member of staff in ensuring the correct consent forms for particular treatment scenarios are completed by patients. **Further action required.**
Counselling should be offered regarding the implications of receiving treatment following consent to parenthood, prior to treatment being provided. Licence Condition T60, T61 & T62.	The PR should ensure counselling is offered.	Evidence was obtained at inspection that legal parenthood is discussed as part of the patient's implications counselling sessions. **No further action required.**
There is no documented procedure for obtaining valid written consent in general. Licence Condition T15, T33. Guidance Note 6.8.	The PR should ensure that an SOP is developed for consenting patients. The PR should consider developing checklists to use to ensure all relevant consents have been	The centre has an "Information and consent" SOP, but the Inspectorate considered that the SOP would not effectively support a new member of staff in ensuring the correct

Area for improvement	Action required	Action taken as evidenced during this inspection
	obtained prior to treatment.	consent forms for particular treatment scenarios are completed by patients. **Further action required.**
Accuracy of information submitted to the HFEA via self assessment questionnaire (SAQ). Directions 0008.	The PR should ensure that the information provided in the SAQ is a true and accurate reflection of activities and processes in place at the centre prior to submission to the HFEA.	The SAQ submitted provided a suitably accurate reflection of activities and processes in place. **No further action required.**
The centre's multiple birth minimisation strategy (MBMS) is not compliant with Directions 0003. Directions 0003.	The PR should ensure that the centre's MBMS is compliant and applied in accordance with all aspects of Directions 0003.	After the last inspection, the centre provided a revised MBMS, including criteria for patient selection. The centre provided records of summary logs where a) two embryos are transferred where the patient meets the criteria for one embryo transfer and b) all cases where three embryos are transferred. The Executive has monitored the centre's progress towards a reduction in multiple births. **No further action required.**
Quality indicators/objectives have not been established for all activities. Licence Condition T35.	The centre should establish quality indicators/objectives for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence.	Quality indicators have been established with the exception of those for the process of donor recruitment and selection. **Further action required.**
Audits against compliance with approved protocols, regulatory requirements and quality indicators have not been performed in the last two years for: counselling provision, information provision, consent, welfare	The centre should audit all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence. The PR should ensure these audits are	The PR confirmed after the last inspection that audits have been performed, and evidence was submitted to the Executive. One exception was seen at inspection: audits of counselling activities

Area for improvement	Action required	Action taken as evidenced during this inspection
of child, donor selection, witnessing, traceability, and data submission to HFEA. Licence Condition T36.	performed in an independent way, at least every two years.	against compliance with the approved protocols have not been carried out **Further action required.**
Completion of all appropriate patient and partner consents. Directions 0007.	The centre should ensure all required consent forms are completed and filed in records and that separate Consent to Disclosure is taken from each partner.	An audit of consent forms carried out at inspection demonstrated that treatment consent forms were completed appropriately. **No further action required in relation to treatment consents** Discrepancies were noted between consents in patient records and in information submitted to the HFEA in relation to consent to disclosure of information to researchers and further action is required in relation to this aspect of the consent process.
WoC assessment and re-assessment in accordance with circumstance. Licence Condition T15 (a) & (d) and T56.	The centre should ensure the staff are informed and competent to ensure the WoC SOP and assessment encompasses all elements of Licence Condition T56 and in accordance with CoP guidance note 8, including the requirement for reassessment.	Refer to main body of report. **No further action required.**
Not all staff could provide evidence of competence assessment/training for relevant processes. Competence assessment/training for counselling provision, information provision, consent, traceability and data submission are not performed. Staff could not provide	The PR should ensure that all relevant staff training and competence assessments are provided and evidence recorded. The PR should ensure that members of staff receive adequate opportunity for relevant professional development, including training regarding changes	Evidence of competence assessments for information provision, obtaining consent, traceability and data submission was provided. Refer to main body of report for further information. **Further action required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
evidence that training has been updated as required when regulatory requirements have changed. Licence Condition T12 and T15.	to regulatory requirements.	
Critical transport conditions (e.g. temperature and time limit) for gamete/embryo distribution have not been defined. Licence Condition T24.	The centre should revise the relevant laboratory SOP. The PR should ensure that where equipment or materials affect critical processing or storage parameters (e.g. temperature) they are identified and the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times.	Evidence was provided that the dry shipper is monitored regularly and the revised SOP specifies the time limit for transport. **No further action required.**
There is no effective recall procedure in place, or a documented system for handling of returned material once gametes/embryos have been distributed. Licence Condition T122.	The centre should revise the relevant laboratory SOP. The PR should ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.	A revised SOP was submitted that includes details for the recall of material. **No further action required.**
SAQ states equipment monitoring is “almost compliant”. Licence Condition T24.	The PR should ensure all equipment affecting critical processing or storage parameters are the subject of appropriate monitoring, alerts, alarms and corrective action.	Staff provided documented evidence that all equipment that effects critical processing or storage parameters are subject to monitoring, alerts and alarms (Licence Condition T24). **No further action**

Area for improvement	Action required	Action taken as evidenced during this inspection
		required.
Reporting of adverse incidents. No adverse incidents have been reported to the HFEA since 2007. Section 17 of the HFE Act 1990 (as amended). Licence Condition T120. Directions 0011.	The PR should ensure that adverse incidents and near misses, including OHSS requiring hospital admission and with a severity grading of severe or critical, are reported to the HFEA within the timeframes specified in Directions 0011. The PR should ensure all previous incidents are reported to the HFEA.	The centre's non-conformance log was reviewed at inspection and indicated that all reportable incidents had been reported to the HFEA, including OHSS admissions. **No further action required.**
The laboratories used to undertake diagnosis/investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them are not CPA accredited. Licence Condition T21.	The centre should ensure that the laboratories used to undertake diagnosis and investigation of samples is accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard.	The PR has confirmed the laboratories used for diagnosis and investigation are CPA (UK) Ltd accredited. **No further action required.**
The current Certificate of Licence is not displayed at the licensed premises. Licence Condition T5.	The PR should ensure that the correct Certificate of Licence is displayed at the centre.	The current Certificate of Licence was observed on display at inspection. **No further action required.**
Grade A air quality has been demonstrated in the workstations, but the air quality of the background environment was last tested 02/08/07. Licence Condition T72.	The PR should validate the air quality monitoring protocol, for the frequency of testing.	Air quality monitoring equipment is in place and air quality of both critical working areas and background environment was seen at inspection to be monitored on a monthly basis. **No further action required.**
The gamete/embryos storage facilities are in a separate block from the treatment and laboratory facilities. Guidance Note 25.7 & 25.14.	The centre should conduct a risk assessment for the movement of samples from the laboratory to the cryoroom.	The centre has provided a risk assessment for the use of liquid nitrogen and a "Transporting cryopreserved material between labs" SOP is in place. **No further action required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
It was discussed at inspection that the Clinical Laboratory Manager's job description does not accurately reflect her duties. Licence Condition T13.	Due to the number of staff changes that have occurred at the centre over the past year, the PR should ensure the job descriptions of all staff accurately reflect their new tasks and responsibilities.	A revised job description for the Clinical Laboratory Manager was submitted to the Executive. The quality manager confirmed that all staff have job descriptions and a sample was seen at inspection. **No further action required.**
Other areas		
There are no separate lockers for staff to securely store their personal belongings. Guidance Note 25.15c.	The centre should consider providing secure storage for staff personal belongings within the centre.	Staff lockers have been installed and were observed at inspection. **No further action required.**
A low oxygen alarm is present in the cryostore, but the door has no vision panel. If the low oxygen alarm were activated, there would be no way of determining safely if a person were present in the room but incapacitated. Guidance Note 25.7.	The PR should risk assess the need for a vision panel to be fitted.	A vision panel was seen to be fitted to the cryostore door. **No further action required.**
The Quality Manager stated at inspection that a management review has not been held and the centre's quality objectives are currently 'on hold' during the centre's staff transition phase. Guidance Note 23.3.	The PR should ensure the quality management system is established and maintained by: (c) establishing quality objectives and plans (g) conducting management reviews of the system.	Reviews of the quality management system were held in February and October 2010 and quality indicators established. **No further action required.**
Not all documents were seen to have been reviewed within one year. Licence Condition T34 and Guidance Note 31.4/6.	The PR should consider the guidance in the Code of Practice that documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The	The centre's document control policy states that all documents are to be reviewed annually and all documents seen at inspection had been reviewed within the last

Area for improvement	Action required	Action taken as evidenced during this inspection
	maximum interval between reviews should be 12 months.	year. **No further action 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 direct risk of causing harm to a patient, donor or to an embryo. 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 noted at the time of this inspection.			

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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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
Quality indicators/objectives have not been established for donor recruitment and selection processes. Licence Condition T35.	The PR should ensure quality indicators are established for donor recruitment and selection processes. By the time the PR responds to this report.	The QI for donor recruitment and selection have now been established (attached)	The centre has submitted a revised "Clinic quality indicators" SOP including QIs for donor recruitment and selection. No further action required.
Not all consumables used in the laboratory are CE marked. Licence Condition T30.	The PR must ensure that wherever possible, only CE marked medical devices are used. 20 January 2011.	A plan for gradual introduction of CE marked lab consumables has been created and agreed with the HFEA and is being implemented over several months (see attachment).	The centre has proposed a plan for a phased introduction of CE marked consumables to allow the centre to assess the impact of the introduction of each new consumable prior to the introduction of

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			another. The centre is aiming for completion by 30 April 2011. The Executive agreed that this would be good practice and has accepted the plan. It is recommended that the Executive continues to monitor progress.
The centre has an "Information and consent" SOP, but this does not describe in detail the process to follow when providing information prior to consenting patients or the process to follow when obtaining consent. The Inspectorate considered that the SOP would not effectively support a new member of staff in ensuring the correct consent forms for particular treatment scenarios are completed by patients. Licence Condition T33 (b).	The PR should ensure the SOP is revised to detail the process to follow when providing information prior to consenting patients and the process to follow when obtaining consent. 20 January 2011.	The SOP has been amended and now describes which forms are to be used in which situation (attached).	The centre has submitted a revised "Information and consent" SOP. This has been reviewed by the Executive and considered satisfactory. No further action required.
Not all errors identified after the EDI forms are submitted to the Authority are cleared within the required two calendar month period. Directions 0005.	The PR should review the processes undertaken to clear error reports and ensure that all errors are cleared within the required period.	A designated person has been employed in December 2010 on a fixed term contract to ensure timely reporting to the	It is recommended that the Executive continues to monitor progress.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	20 April 2011.	HFEA including error correction.	
Licensed Treatment Reporting An audit of 134 treatments undertaken between 01/09/09 and 31/08/10 found that ten (8%) IVF and one DI treatment had not been reported to the HFEA. Only seven (6%) were reported to the HFEA within 5 working days of treatment as required by Direction 0005. A review of 54 sets of assorted form data submitted to the Authority between 01/09/09 and 31/08/10 against source documentation held on patient and donor files found that 23 (43%) contained error or omission. No errors were found in critical fields (e.g. a donor reference) that could affect the Authority's ability to fulfil obligations to offspring. Directions 0005.	The PR should review the processes undertaken to submit treatment data to the Authority and revise accordingly to ensure compliance with the reporting periods stipulated within Directions 0005. All errors and omissions to be corrected. The PR should submit a plan by 20 January 2011 for achieving improvement of the quality of the centre's treatment reporting to the HFEA.	A designated person has been employed in December 2010 on a fixed term contract to ensure timely reporting to the HFEA including error correction. In addition a casual staff has been assigned to correct errors. Correction of errors is currently ongoing.	The Executive notes the PR response but requires that the centre submit a detailed plan for achieving improvement of the quality of the centre's treatment reporting to the HFEA by 20 January 2011. The plan should include the processes that will be put in place to ensure all treatments are reported, that they are reported within 5 working days and with no errors. It is recommended that the Executive continues to monitor progress.
Consent to the use of information held on the HFEA Register for use in research	The PR should audit the consent to disclosure of identifying information from the	An audit of the consents has been initiated and is progressing. Patients who	An update was received from the centre on 17/12/10:

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The bulk of the errors found, referred to above, related either to discrepancies between patient and partner consent to the disclosure of register information for research purposes, or the lack of evidence to support the disclosure consent recorded by the centre on patient and partner registration forms submitted to the Authority. Directions 0005, paragraph 8 and Directions 0005, paragraph 9.	HFEA register in the patient records against the decisions which have been submitted to the HFEA register via the EDI system. Discrepancies will need to be corrected. This audit will need to encompass all patients for whom consent to disclosure has been submitted over the EDI system. The PR should ensure that in the future, all data submitted through the EDI system regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record. This action should be completed by 20 January 2011 and a report provided to the Executive by 3 February 2011.	have not given consent will be identified for action. The audit will be finished by 20/1/11.	"The audit of 'Consent to disclosure' has allowed us to identify patients who have not given consent (i.e. distinct from declined to give consent) and they will be contacted and given a consent form and the data amended. The incorrect data in the HFEA submissions will be corrected". It is recommended that the Executive continues to monitor progress.

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 good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Audits of counselling activities against compliance with the approved protocols have not been carried out. Licence Condition T36.	The PR should ensure that audits of counselling activities against compliance with the approved protocols are carried out. 20 April 2011.	An audit was done in May-Nov 2009 (attached) and a similar one was run in Mar-Aug 2010. The analysis has however not been finalised.	The centre has submitted audits of patient satisfaction with the counselling service. The centre has stated that these audits indicate if the end users, the clients, are satisfied with the service and that audits of counselling uptake will indicate if usage is “normal”. Counselling supervisors will issue a statement regarding whether or not the counsellors meet the competence criteria listed by BICA by the end of March 2011. It is recommended that the Executive continues to monitor progress.
Some samples of gametes and embryos are labelled with only the patient’s surname and unique identifier.	The PR must ensure that all containers used in the course of procurement, processing, use	Implemented (see attachment).	The centre has confirmed that: • All containers are

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Licence Condition T101 and CoP guidance 18.20.	and storage of gametes and embryos are labelled with the patient's/donor's **full** name and unique identifier. 20 January 2011.		now labelled with the patient's full name and unique identifier. • SOPs have been amended. • Embryologists and all staff involved in witnessing have been informed of the changes. Two revised SOPs have been submitted that document the use of the patient's full name. No further action required.
The centre has a third party agreement with a courier company for the transportation of gametes and embryos. The third party agreement does not define the critical transport conditions nor has the requirement for the maintenance of those conditions been documented. Licence Condition T114 (e).	The PR should ensure that the third party agreement defines the critical transport conditions and the requirement for maintenance of those conditions. 20 April 2011.	Effort underway to get response from service provider (see attachment).	The centre has confirmed that a new third party agreement specifying critical transport conditions has been drawn up and sent to the courier company. It is recommended that the Executive continues to monitor progress.
Nursing staff cannot provide documented evidence of the assessment of their competence in all designated tasks.	The PR should ensure that all staff can provide documented evidence of the assessment of	The assessment of competence for all licensed nursing	The centre has submitted a detailed plan for documenting

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Further progress is required to ensure the nursing competence framework is reflective of current nursing duties, including clinical procedures A counselling competence framework template was provided by the centre, but has not yet been initiated. Licence Condition T15 (a).	their competence in all designated tasks. The PR should submit a detailed plan, including a summary of all nursing and counselling staff and the competence assessments they need to complete, including timeframes, before the report is to be considered by the Executive Licensing Panel. The PR should submit quarterly reports to the centre's inspector regarding the progress of implementation of this plan until it is completed.	activities is partly completed and will continue with an aim to be completed at the end of January 2011(see attachment).	competence assessments of nursing and counselling staff. It is recommended that the Executive continues to monitor progress.
The centre's adverse incident policy does not specify that incidents should be reported to the HFEA within 24 hours. Licence Condition T33 (b). Directions 0011.	The PR should ensure that the written protocol specifies the timeframe for reporting incidents to the HFEA. By the time the PR responds to this report.	Amended (see attachment).	The centre has submitted a revised "Incident reporting policy and procedure manual" documenting the timeframe for reporting incidents to the HFEA. No further action required.
The centre's "Donor schemes" SOP patient information section states that "presently the law does not allow the children who may apply for information from the HFEA register to know the	The PR should ensure that the SOP detailing the information to give to patients clarifies the information that can be obtained by donor conceived	Amended (see attachment).	The centre has submitted a revised "Donor schemes" SOP clarifying the information that can be obtained by

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
identity of the donor". It does not clarify the information that can be obtained at 16 and 18 years of age The SOP also states to explain to the donor that they "may change their mind at any time". Interpretation of mandatory requirements 5H states that consent can be varied or withdrawn at any point until the gametes or embryos are used to provide treatment services.	children and the point at which donors may vary or withdraw their consent. 20 January 2011.		donor conceived children and when consent can be varied or withdrawn. No further action required.
The centre does not have an SOP documenting the procedure to be followed for withdrawal of consent to being the legal parent. Licence Condition T33 (b).	The PR should ensure that an SOP for the procedure to be followed for withdrawal of consent to being the legal parent is developed. 20 January 2011.	Amended (see attachment).	The centre has submitted a revised "Information and consent" SOP that includes a section on withdrawal of consent to being the legal parent. No further action required.
The centre does not have an SOP for the control of access to health data and records. Licence Condition T44.	The PR should ensure that an SOP is established covering all requirements of Licence Condition T44. 20 April 2011.	Amended (see attachment).	The centre has submitted a "Protecting confidentiality at NURTURE" SOP and a "Request for copies of patient records" SOP. No further action required.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

14 January 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0076 (NURTURE) - Renewal Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Helen Richens – Policy Manager	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 has been licensed by the HFEA since 1992, and offers a comprehensive range of licensed treatments to both self funding and NHS contracted patients from Nottingham and surrounding counties.

2. The Panel noted that the centre is located within the campus of Queens Medical Centre which is part of Nottingham University NHS Trust.

3. The Panel noted that the centre is considered by the Inspectorate to be of moderate size, offering approximately 550-600 licensed treatment cycles per year.

4. The Panel noted that the Person Responsible (PR), Mr James Hopkisson, is a sub specialist in Reproductive Medicine and has been on the speciality register of the General Medical Council for Reproductive Medicine, Obstetrics and Gynaecology since 2002.

5. The Panel noted that Mr Hopkisson is the Director of NURTURE and has satisfactorily completed the PR entry programme, and has held the post of PR since 2003.

6. The Panel noted that at the time of the inspection on 20 October 2010 there were a number of areas of practice identified that required improvement, including five major areas of non-compliance and eight other areas of non-compliance.

7. The Panel noted that since the inspection the PR has taken steps to address some of the recommendations made in the report and provided evidence that, in the view of the Inspectorate, means that the centre is now compliant with the recommendations specified on page five of the report.

8. The Panel noted in particular that the PR has now established quality indicators for donor recruitment and selection processes and has also revised the centre's information and consent standard operating procedures.

9. The Panel noted that the remaining areas of concern set out on page six of the inspection report; notably, that the PR ensures that CE marked medical devices are used, and that the processes undertaken to submit data to the Authority are reviewed and revised to ensure compliance with the reporting periods stipulated within Directions 0005.

10. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a period four years without any additional conditions.

11. The Panel had regard to its decision tree. It was satisfied that the application was submitted in the form required, and contained the supporting information required by General Direction 0008. It was also satisfied that the appropriate fee had been paid.

12. The Panel was satisfied that the application designated an individual to act as the Person Responsible (PR) and that the PR had consented to act as such.

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

14. 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.

15. 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.

16. The Panel was satisfied that the application does not involve the use of embryos for training purposes, nor does it involve testing of embryos.

Decision

17. 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.

18. As it was satisfied that the evidence before it revealed no concerns regarding the requirements set out in paragraph 4.3, the Panel agreed to renew the centre's treatment and storage licence for a period of four years with no additional conditions.

19. The Panel endorsed the recommendations made by the Inspectorate, and urged the PR to ensure that all outstanding recommendations are rectified within the specified timeframes specified.

Signed: Peter Thompson Date: 25/1/11.
Peter Thompson (Chair)