Inspection Report

Date of Inspection: 29 February and 1 March 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 13 hours
Inspectors Parvez Qureshi
Andy Glew
Tony Knox

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 30 April 2009 and 18 May 2012.

Date of Executive Licensing Panel: 1 June 2012

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	CREATE Centre for Reproduction and Advanced Technology
Centre number	0299
Licence number	L/0299/2/c
Centre address	3-5 Pepys Road, West Wimbledon, SW20 8NJ,
Person Responsible	Professor Geeta Nargund
Licence Holder	Professor Stuart Campbell
Date licence issued	01/08/2009
Licence expiry date	31/07/2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
CREATE Centre for Reproduction and Advanced Technology has been licensed since August 2008. The current licence was granted on 1 August 2009 and will expire on 31 July 2012. The centre has a good history of compliance with no previous conditions on its licence.

At the time of the last inspection in April 2009 the centre consisted of two separate sites. The main site housed the laboratory facilities where all the licensed activities took place and a second site which was used for administrative purposes. However, since then the administrative site has been closed and all functions have been transferred to the main site. The premises provide a well maintained and suitable environment for patients, centre staff and clinical and laboratory processes.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 February 2011 – 31 January 2012*
In vitro fertilisation (IVF)	475
Intracytoplasmic sperm injection (ICSI)	254
Frozen embryo transfer (FET)	56
Donor insemination (DI)	19
Egg share provider (sharer)	5
Egg share recipient	5
Egg donation (non-egg share)	2
Partner insemination	58 1 January to 31 December 2011)

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period November 2010 to October 2011 show the Centres success rates are in line with national averages.

For the year 2011 the centre reported 58 cycles of partner insemination with one pregnancy. **

*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.

**These data were provided to the HFEA after the deadline required by Directions and as a result the statistical analysis of the outcomes has not been carried out. This analysis will be completed retrospectively and if this does not represent performance in line with sector averages then this will be followed up by the inspection team.

Summary for licensing decision

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

- the PR is suitable and has, with the exception of the areas of non-compliance identified in this report, discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major area of non-compliance and two other areas of non-compliance or areas of poor practice.

Since the inspection visit on 28 February and 1 March 2012 the PR has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR to ensure that all equipment that affects critical processing or storage parameters is alarmed.
- The PR should ensure that all critical processes are validated.
- The PR should ensure that quality indicators (QIs) or objectives relevant to all activities authorised by this licence are established and conduct regular audits for them.

Other areas of practice that require improvement:

- The PR to ensure that the content of all the third party agreements are compliant and meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice (CoP).
- The PR to ensure that the centre's import and export standard operating procedure (SOP) is updated to include current references to the HFEA Directions.

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

Major areas of non compliance:

- PR should ensure all licensed treatment cycles are reported within the required timeframe to the HFEA.

The inspection team recommend the renewal of the centre's licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

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.

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

What the centre does well.

Witnessing – (Guidance Note 18)

The centre has a SOP in place for the process to be followed when carrying out witnessing (Standard Licence Condition (SLC) T33(b)). A review of the witnessing SOP and discussions with laboratory staff demonstrated that processes are in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. The scientific inspector noted in patients' medical records that the witnessing checks are carried out and documented appropriately at the time the procedure takes place. Further evidence of this was also noted by the scientific inspector during observation of a sperm preparation being conducted by laboratory staff (SLC T71).

Five sets of patients' notes were audited for witnessing during the inspection. All were found to contain a record of all required witnessing checks which included the names, status and signatures of staff performing the checks (Code of Practice (CoP) Guidance 18.8).

Evidence was provided to the inspection team showing that the centre has established quality indicators (QIs) relevant to witnessing; reports of audits performed were observed for December 2011. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing (SLC T15 (a)).

What the centre could do better.

Nothing noted at the time of inspection.

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Discussion with staff and an audit of patients' notes during the inspection found justification for treatment, medical history and laboratory test results for all patients having treatment at the centre. Evidence was provided by laboratory staff to show blood tests for patients are undertaken in a laboratory which has been accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T21).

Counselling - (Guidance Note 3)
Nursing/medical and counselling staff confirmed that counselling is offered to all patients providing consent. Those entering a treatment cycle requiring a gamete donor or surrogacy are required to see the counsellor prior to the commencement of treatment. All donors are required to see the counsellor also as part of the acceptance criteria (Act schedule 3, S.3 (1)(a).

An audit of ten patient records demonstrated that the offer and uptake of counselling is documented. The centre has established QIs for counselling; reports of audits performed were observed for January 2012. No corrective action was required (SLCs T35 and T36).

A SOP was provided at inspection for the provision of counselling. The SOP describes the referral process and the type of counselling offered (SLC T33b).

The centre's counsellor is fully qualified and has sat on the board of the British Infertility Counselling Association (BICA) and has been an accredited member of BICA for a number of years. She has extensive experience in this field, has supervision by two independent counsellors/mentors. Also, she is included in all discussions related to counselling within the clinic by the PR (SLC T15 (a)).

The Head of Nursing confirmed that centre can refer patients for specialist counselling, if required.

What the centre could do better.

Nothing noted at the time of inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
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.

Donor recruitment, assessment and screening - (Guidance Note 11)
The centre has donor recruitment, assessment and screening SOPs in place which document the clinical processes to be followed (SLC T33(b)).

At the time of this inspection, there was only one current sperm donor who had been recruited at the centre. Donor registration forms were seen for this donor. Also, it was noted that all screening undertaken was in accordance with current professional guidelines and was carried out by an external laboratory which is CPA accredited. Evidence of all required testing were contained in the notes (SLC T53(a)).

The PR also reported that procedures were in place to identify when additional screening tests may be required (SLC T52(g)). Further to this, the clinic had recently undergone a recall of all donors and patients who had not previously been tested for core antibodies. This program had been completed and all test results were contained in the notes audited during the inspection. Staff interviewed confirmed that the required period of quarantine is observed for donor sperm samples (SLC T53(c)).

Payments for Donors - (Guidance Note 13)
Documented evidence was seen in the donors' records showing that money or other benefit given to the donor was in compliance with Directions 0001. Nursing staff reported that where the donor is introduced to the clinic by the recipient, they are questioned to ensure that no payments are made between the two that would constitute a non-compliance with Directions 0001. Also, The nursing staff report that receipts (where provided) would be stored within the patients' notes where payment had been made.

Donor assisted conception - (Guidance Note 20)
Patients receiving treatment with donated gametes are provided with information, in written form and verbally, by staff and a counsellor on the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not their parent. (SLC T63 (a)).

With regard to information on how to tell any resulting child at an early age that he or she results from the gametes of a person who is not their parent, the counsellor reported that this is a topic which is discussed extensively during her counselling sessions with the patient (SLC T63 (a)).

The centre has only used donor gametes or embryos created using gametes from identifiable donors and there are there are no donors registered at the centre pre 2005 (SLC T54).

What the centre could do better.

The centre has not established QIs relevant to donor recruitment, assessment and

screening. Also, procedures for recruiting donors have not been audited (SLCs T35 and T36).

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)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

The quality management system – Guidance Note 23
The centre has a quality management system (QMS), which incorporates the HFEA licensed activities undertaken by the centre (SLC T32).

The QMS consists of a quality manual and training and reference manuals, as required by SLC T33. The centre has established objectives and key performance indicators for licensed activities and has conducted ongoing audits. Evidence of audits for provision of information, consent, WoC and witnessing were seen. The findings of the audits and, where required, the corrective actions taken were also seen (SLC T36).

A process is in place for the annual review of the performance of the QMS to ensure continuous and systematic improvement. Evidence of this was submitted as part of the renewal application for an annual review conducted in June 2011.

The centre has a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed during the course of the inspection.

Traceability - (Guidance Note 19)
The centre has a process in place to ensure all gametes and embryos are traceable from procurement to patient treatment or disposal (SLC T99). All relevant data relating to anything coming into contact with those gametes or embryos is traceable.
Containers are, at all stages of procurement, processing and storage, labelled with the patient's full name and a unique identifier (SLC T101). Staff reported that the centre has a procedure in place to ensure data necessary for traceability is stored for at least 30 years (SLC T103).

There is a documented SOP in place to ensure traceability (SLC T33(b)).

The centre has established QIs relevant to traceability; reports of audits performed were observed for April 2011. Where required, corrective actions had been documented and implemented (SLCs T35 and T36).Laboratory staff were able to provide documented evidence of training in traceability procedures (SLC T15 (a)).

Process Validation - (Guidance Note 15)
Laboratory staff provided evidence of validation of a number of critical procurement and processing procedures which influence the quality and safety of gametes and embryos (SLC T72)

Equipment and materials - (Guidance Note 26)
Laboratory staff provided documented evidence of the regular cleaning and disinfection of equipment, the maintenance and regular inspection of equipment in accordance with manufacturer's instructions. Records of annual servicing of flow hood demonstrated this. Documented procedures for the operation of all critical equipment were seen by the scientific inspector. All critical equipment has been validated, comprehensive evidence of equipment validation was seen including that for temperature monitor validated in October 2010. Also, documented evidence was seen for the revalidation of a syringe pump following repair. All equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms (with the exception detailed below). Incubator logs of temperature and carbon dioxide concentrations were seen to be maintained (SLCs T23, T24, T25, T26 and T27).

Only sterile equipment is used for the procurement of gametes and embryos. Laboratory staff reported that equipment used for the procurement of gametes and embryos was of good quality, validated or specifically certified and regularly maintained. Also, where possible the centre uses CE marked equipment (SLCs T28 and T30).

Premises – suitability of the premises and air quality (Guidance Note 25)
The activities authorised by the licence are carried out in the premises specified in the licence (SLC T1). The PR reported that some scanning work is conducted at the Harley Street Clinic offices. All licensed premises are located within the same building. Since the last inspection, the main front entrance to the clinic has been moved. There is a ramp and steps leading to the front door of the unit. Access can also be gained to the unit from the car park at the rear of the clinic. Both doors are attached to a door security system where a bell is pressed which activates a buzzer in the main reception area. Entry is only permitted by door release from the reception area.

Review of documents submitted for the inspection and discussions with the laboratory staff showed that the critical work area where gametes and embryos are processed achieves Grade C air quality, with a background within the laboratory of Grade D air quality. The critical work area is subject to annual checks on air quality and quarterly for microbial contamination (SLC T20).

Adverse incidents - (Guidance Notes 27)
A documented procedure for the reporting of adverse incidents to the HFEA was seen during the inspection (SLC T118). The centre has reported all the required incidents to the HFEA since the last inspection in April 2009. The PR was able to demonstrate the process for reporting and dealing with adverse incidents. The PR also reported that other members of staff were aware of the process of reporting incidents to the HFEA within the required timeframe.

Third party agreements - (Guidance Note 24)
A list of all third party agreements established with third parties who provide goods and

services that influence the quality and safety of gametes and embryos was seen by the inspection team (SLCs T111 and T115). The laboratory manager reported that no issues have arisen with regard to the ability of third parties to meet the required standards (SLC T112).

What the centre could do better.

Equipment and materials - (Guidance Note 26)
Two incubators were not alarmed (SLC T24).

Third party agreements - (Guidance Note 24)
An audit of third party agreements showed that the content of some of the third party agreements are not fully compliant with requirements (SLC T114 and T116).

Multiple Births (Guidance Note 7)

For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 30%: this represents performance unlikely to be different from the target at a statistically significant level[1]

What the centre does well

On-going monitoring of the centres multiple clinical pregnancy rates suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123).

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

What the centre could better

Nothing noted at the time of inspection.

Staff engaged in licensed activity

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

What the centre does well.

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

Person Responsible - (Guidance Note 1)
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme.

Staff - (Guidance Note 2)
An organisation chart is in place which defines accountability and reporting relationships (SLC T11). The centre has access to a registered medical practitioner who is able to advise on and oversee the medical activities (SLC T16). The PR confirmed that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act Schedule 17 (1) (a)).

The PR reported that the centre has assessed the workforce requirements within the last year and confirmed that currently they are operating with a full staff complement. The PR considered that the number of staff is adequate for the current volume of work being undertaken by the centre (SLC T12).

There is a formal induction training programme in place for all staff; evidence of this was seen in the training records for a member of the nursing and laboratory staff. The PR confirmed that all staff are competent in their designated tasks. From documentation reviewed at inspection, staff were able to demonstrate evidence of the assessment of their competence to perform designated tasks and participation in relevant professional development by attending training courses and meetings (SLC T15).

Medical, nursing, scientific and counselling staff are appropriately registered or in the process of registering with their respective professional bodies (SLC T14).

What the centre could do better.

Staff - (Guidance Note 2)
All current posts within the unit have been filled. The number of treatment cycles being performed at the centre is increasing, and has increased since the last inspection in April 2009. There are only two qualified and registered nursing staff on site. During busier periods of the centre's operation, these nurses can sometimes work six days per week. In the event that patient number continue to increase, it would be prudent to re-assess the number of staff needed against the numbers of patients being treated (SLC 12).

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child - (Guidance Note 8)
The centre has a SOP in place for the process to be followed when carrying out a welfare of the child (WoC) assessment (SLC T33(b)). WoC assessments were evidenced in ten notes reviewed on the day. These were in date and relevant to the treatment cycle being performed. Discussions with staff (including the counsellor) confirmed the importance of conducting WoC assessments and noted that in the event that there was any concern regarding such an issue, the case would be discussed at an ethics committee meeting prior to agreeing to treatment going ahead SLC T56).

The centre has established QIs relevant to the assessment of WoC and these were audited in December 2011. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff who conduct WoC assessments were able to demonstrate their competence in this process as evidenced in their training and induction programs (SLC T15(a)).

As the centre provides treatment involving surrogacy, WoC assessments are carried out for both the commissioning couple and the surrogate and surrogate's partner where relevant (SLC T56). Evidence of this was seen in a patient's notes containing four sets of WoC consents both from the commissioning couple as well as the surrogate and her partner.

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 costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly - (Guidance Note 29)
The centre has policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner.

Confidentiality and privacy - (Guidance Note 30)
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

Patient records are kept in a secure area and only staff on the centre's licence have access to confidential information. All current notes are kept in the reception office in lockable cabinets (the centre has changed its layout since the time of the last inspection in April 2009 and moved archived notes off site to its sister unit to ensure the security and confidentiality of archive notes) (SLC T43). There is a SOP in place to ensure that information is only disclosed in circumstances permitted by law (SLC T43). A SOP for the control of access to health data and records was also seen and was compliant with requirements (SLC T44). The PR reported that as part of the centre's policy, all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during the inspection (SLC T15(a)).

Complaints - (Guidance Note 28)
There is a complaints procedure in place and staff were able to demonstrate their understanding of how they would resolve a complaint in a timely manner. The PR reported that all complaints are logged, investigated, documented and a formal response is sent to patient. There were three complaints in the log all of which had been closed to the patients' satisfaction. Since the last inspection in April 2009, no complaints have been made to the HFEA.

Provision of costed treatment plans - (Guidance Note 4)
Clinical staff interviewed during the inspection reported that the costs of treatment are prepared in advance of the treatment commencing by the nursing/medical and administrative staff. In the event that an element of the treatment is uncertain, e.g. ICSI may be required, this cost is factored in prior to presenting the final cost of treatment to the patients. If the uncertain element is not required, the cost of this is then returned to the patient at the end of the treatment cycle. Patients interviewed during the inspection reported that they were aware of the costs of their treatment prior to the cycle commencing. Copies of the invoices are held in the patient notes (CoP guidance 4.3).

Egg sharing arrangements - (Guidance Note 12)
The centre has an egg sharing scheme in place and recruits egg sharers donating for treatment purposes only. Documented evidence was seen in two egg sharers records to show that the donation had been made in the same cycle as the treatment (Directions 0001). During the discussion with the Head of Nursing, it was ascertained that donors and recipients are provided with consultations at different times to ensure that their confidentiality is maintained.

Surrogacy - (Guidance Note 14)
The gamete providers in surrogacy arrangements are screened as donors, evidence of this was seen in patient records. Also, evidence of all required testing was found to be present in the notes along with the required quarantine period (SLC T53(c). The centre registers the gamete providers in surrogacy arrangements as donors; evidence of this was seen in patient records (Directions 0003).

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 Intracytoplasmic sperm injection (Guidance Note 21)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information - (Guidance Note 4)
Information provided at the time of inspection, including an audit of ten patient records; an audit of patient information material submitted for the inspection; discussion with staff; patients and the review of the responses from the HFEA patient questionnaire showed that relevant information is provided to patients before treatment is provided. The centre's website was also reviewed and found to be compliant with Chair's letter CH (11)02 and the Code of Practice (CoP).

There is a SOP for the process to be followed when providing information to patients prior to consenting to treatment (SLC T33(b)).

The centre has established QIs relevant to the provision of information and these were

audited in January 2012. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff were able to provide documented evidence of their competence to provide information for those consenting to treatment (SLC T15(a)).

What the centre could do better.

Nothing noted at the 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.

Consent – (Guidance note 5)
Written consent is obtained before gametes or embryos are used in treatment or stored, this was noted during review of ten patients' notes and the laboratory worksheets. This was also confirmed by the patients interviewed during the inspection. There is a SOP in place for the process to be followed when obtaining consent. A checklist is also kept in the notes to capture that consent forms are discussed with patients during medical consultations (SLC T33(b)). Staff confirmed that the identity of the person providing consent is verified, photographic evidence is included in patient records (CoP 5.10). Staff reported that the identity of the person who gave consent is also cross referenced to the records before treatment is provided (CoP 5.11).

The Head of Nursing confirmed that where there is potential uncertainty that ICSI may be required, prior to commencing treatment, the implications of this are explained and the patients are consented prior to going to the treatment room for the procedure. In this way the patients are fully aware of the possibility of additional practices being required without the need for the patient to have to consent to these additional procedures either under the influence of sedative or under duress.

Evidence was provided by staff showing that the centre has established QIs relevant to obtaining consent and these are audited and where required corrective actions are documented and implemented (SLCs T35 and T36). A report of the consent audit conducted in September 2011 was made available on inspection.

The centre has a procedure in place to ensure that all stored gametes and embryos are within their statutory and consented storage periods, evidence of this was seen by the scientific inspector.

The centre's procedure for withdrawal of storage consent includes the provision of a 12 month 'cooling off' period in cases where one gamete provider withdraws consent to embryo storage. Nursing staff interviewed were able to demonstrate their understanding of the 'cooling off' period and they reported as yet this this has not been necessary.

Nursing staff provided documented evidence of the assessment of their competence to take consent. Evidence of this was seen during review of staff records (SLC T15a).

Consent to legal parenthood - (Guidance Note 6)
The centre has a SOP in place to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos (SLC T33(b)). Evidence was seen in the notes where consent to legal parenthood had been signed. The counsellor confirmed that issues surrounding legal parenthood are discussed during the counselling sessions that she provides.

Discussion with staff at the centre confirmed that processes are in place to ensure that further treatment is not carried out where one prospective parent has withdrawn consent. (SLC T64(b)). The Head of Nursing reported that there had been no such cases at this centre since its opening.

What the centre could do better.

Nothing noted at the time of inspection.

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 were 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 inspection team considered that all staff interviewed displayed in their responses appropriate respect for the special status of the embryo when carrying out licensed activities. Also all gametes and embryos are procured and used in a lawful manner, with appropriate consent.

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.

Storage of gametes and embryos - (Guidance Note 17)
The centre has a SOP in place documenting the process to be followed when storing gametes and embryos (SLC T33(b)).

Evidence was provided by laboratory staff that the centre has established QIs relevant to storage. Reports of dewar audits for sperm and embryos were observed for 2010. Where required corrective actions were documented and implemented (SLCs T35 and T36). Documented evidence was observed for laboratory staff of the assessment of their competence in storing cryopreserved material (SLC T15a).

Nine sets of patients' notes were audited in relation to consent to storage of gametes and embryos during the inspection. All were found to contain evidence that cryopreserved gametes and embryos were within the consented time period. The centre operates a bring-forward system to ensure that samples are not stored beyond their consented storage period (HF&E Act (1990) as amended, 14(1)(c)).

Prior to storage, gamete providers are screened for HIV 1 and 2, and hepatitis B and C. In the event of any positive results the centre has facilities to store samples separately (SLC T50(b)). All screening tests are carried out by a laboratory which is accredited by CPA (SLC T51(a)).

What the centre could do better.

The vitrification process has not been validated (SLC 72).

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 and receipt of gametes and embryos
The centre has a SOP describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLC T33(b) and T107). The centre uses checklists to ensure the procedure is followed accurately and that all required information is provided (SLC T110). Containers and packaging have been validated as fit for purpose (SLC T108).

The SOP also defines the responsibilities and actions that would be required if a distribution was recalled, including the investigation of the recall as an adverse incident. The centre has third party agreements in place with couriers that ensure the required conditions are maintained during the distribution of samples (SLC T111).

Import and export of gametes and embryos (Guidance Note 16)
Between January 2011 and January 2012 the centre has imported 53 and exported 2 sperm samples. Also, three embryos were exported. The staff confirmed that the samples were imported and exported with the appropriate documentation to satisfy the PR that the requirements of HFEA Direction 0006 had been met. A review of the supporting documentation confirmed that the requirements of General Direction 0006 had been complied with.

What the centre could do better.

Distribution and receipt of gametes and embryos
A third party agreement with one of the couriers was not fully compliant with requirements of the relevant licence conditions (SLC T116).

Import and export of gametes and embryos (Guidance Note 16)
The import and export SOP requires updating to include current references to the HFEA Directions (SLC T33(b)).

4. Good governance and record keeping

Focus

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

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

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Record keeping and document control: Guidance Note 31
All patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

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.

Obligations and reporting requirements of centres – Guidance Note 32
The PR provided all information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner.

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 1/11/2011 and 31/10/2011 was reviewed. The sample was drawn from the centres records and was reviewed against an extract of the Authority's statutory register.

The sample comprised 160 treatments and was drawn from treatments spreadsheets which the centre maintains.

Data Quality

To ascertain the quality of the data submitted by the Centre for inclusion on the statutory register, a review of 87 assorted data forms submitted to the Authority between 1/11/2011 and 31/10/2011 against source documentation held on patient and donor files was conducted. A small number of errors were found including one related to donor height which appeared to be a technical problem.

No errors were found that could affect the Authority's ability to fulfil statutory obligations to offspring (i.e. failure to indicate the use of donor gametes in an IVF treatment). The audit sample was too small to conclude whether system or process errors are the cause of the errors identified as opposed to simple input error.

What the centre could do better.

Licensed Treatment Reporting

Two (2%) of the 122 IVF treatments and four (11%) of the 38 DI treatments in the audit sample were found to be unreported at the time of inspection.

On average 8% of the treatment cycles in the audit sample were reported to the HFEA within 5 working days of treatment as required by Directions 0005. This rate was at 6% for IVF cycles.

All licensed treatment cycles are not reported within the required timeframe to the HFEA (Directions 0005).

Data Quality

A small number of errors were found including one related to donor height which appeared to be a technical problem.

Disclosure of information

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

What the centre does well.

Confidentiality and privacy (Guidance Note 30)
Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that all information is kept confidential and only disclosed in circumstances permitted by law. The centre has processes in place to ensure that access to the centre's health data and records is kept secure at all times and is only available to centre staff named on the centre's licence or authorised by the Person Responsible (SLCs T43; T44 & T45).

Disclosure of information, held on the HFEA Register, for use in research
The centre seeks consent from relevant parties to the disclosure of information held on the

HFEA register to medical or other researchers. During an audit of patient records it was noted that the appropriate HFEA consent to disclosure had been completed in all sets of records. The consents recorded in the patient notes were consistent with the consents reported to the HFEA.
What the centre could do better. Nothing noted at the time of inspection.

5. Changes / improvements since the previous inspection on 30 April 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Establishment of third party agreements with services and suppliers does not meet the requirements of S.4.2.10(b) and standard licence condition A.5.	The centre should ensure that all third party agreements are in place with services and suppliers.	Agreements are in place with third parties who provide good and services that influence the quality and safety of gametes and embryos. However, the content of some of agreements was not fully compliant with requirements Further action required.
The centre shall establish documented procedures for personnel management that ensure that all staff have job descriptions S.6.2.2(a).	All staff working at centre should be issued with job descriptions.	The PR confirmed that job descriptions are in place for all staff. No further action required.
A quality manual is in place. However, implementation of the quality management system (QMS) is not fully compliant with the requirements of S.5.2.4 (a) and S.5.2.4(d)	Full implementation of the QMS is required to make it more effective. This includes updating the quality manual to show the legal identity of the centre and an outline of the processes and documentation required to establish the QMS.	The centre has a QMS in place which appeared to be compliant with requirements. No further action required.
Review current procedures for access to the premises and ensure security of the centre and staff is not compromised S.6.3.2.	PR should review current procedures for access to the premises.	Entrance to the unit has been changed since the last inspection and it is no longer made via the double doors leading directly into the unit from street level, these have been closed. This was an issue at the last inspection due to the entrance being in close proximity to where the notes were being stored and was therefore seen to be unsecure. This is no longer an issue. No further action required.

Review of the appropriateness of the procurement facilities A.6.5.	The PR needs to put measures in place to ensure privacy and dignity are maintained.	A vacant/occupied sign has been put in place. No further action required.
Staff competency and training is not documented S.7.7.2 A.10.11	Personnel must be provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks.	Documented evidence of staff competency was seen. The nursing competencies have been developed using the framework devised by the Royal College of Nursing (RCN). Some further work is now being conducted to assign these at the appropriate levels for the staff working at the centre. No further action required.
Validation of all key processes and procedures has not yet been established S 6.4.2(a), S 7.8.3 and standard licence condition A.11.11	A plan for validation should be drawn up which takes into account the particular needs of the unit and prioritises the validation of those processes considered to be most likely to impact on the quality of the service.	Key processes and procedures have been validated but not all have been documented. Further action required.
The protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21. and S.7.7	The transportation protocol should be reviewed and revised as required to ensure compliance with the recommendations of Alert 21	The transportation protocol has been updated. No further action required.
Witnessing is not compliant with guidelines G.13.1	Review of witnessing procedure to be undertaken.	Witnessing appeared to be compliant with requirements. No further action required.
Access to records and information held electronically is not compliant with guidelines G.10.2	The centre should have clear security procedures to prevent unauthorised access to records. The security procedures should be appropriate for the type of record keeping system, including where information is held on paper, electronically or in any other type of system.	This has been addressed as part of the new entrance to the premises. 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 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 identified 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, 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
Two incubators were not alarmed (SLC T24).	The PR to ensure that all equipment that affects critical processing or storage parameters is alarmed. An action plan to be submitted by the time the PR responds to this report.	Following the inspection, two Minc incubators have been linked to the existing Laboratory alarm system. I can confirm that they are fully alarmed.	The inspectorate considers this to be an acceptable response.
The vitrification process has not been validated. (SLC 72)	The PR should ensure that all critical processes are validated. This action should be implemented by 1 September 2012. An action plan of how this is to be achieved within the required timeframe should be submitted to the lead inspector at the same time that the PR responds to this report.	Following inspection, we realised that HFEA wanted a validation report even when the numbers are very small. Therefore we have completed the validation for vitrification results for our centre.	Following review of the validation document submitted by the PR, the inspectorate considers this to be an acceptable response.
The centre has not established QIs or objectives relevant to donor recruitment, assessment and screening or has conducted regular audits for them. (SLC T35 and T36)	The PR should establish QIs or objectives relevant to all activities and conduct regular audits for them. An action plan to be submitted to the lead inspector by the time the PR responds to this report.	A section has now been added to the CREATE QI & KPI document.	Following review of the QIs document submitted by the PR, the inspectorate considers this to be an acceptable response.

Not all licensed treatment cycles are being reported within the required timeframe via EDI to the HFEA. Directions 0005	PR should ensure all licensed treatment cycles are reported within the required timeframe to the HFEA. This action should be completed by 1 June 2012.	Our compliance has significantly improved. The HFEA needs to recognise and accept the slight delay in reporting of natural cycles. We are implementing IDEAS database within a few weeks. This would certainly ensure full compliance with immediate effect for stimulated cycles.	Following review of the supporting information submitted by the PR, The inspectorate considers this to be an acceptable response and will continue 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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The content of some of the third party agreements are not compliant and they do not meet the requirements of the relevant licence conditions and the guidance set out in	The PR to ensure that the content of all the third party agreements are compliant and meet the requirements of the relevant licence conditions and the guidance set out in the HFEA	The third party agreement is now fully compliant and signed by both parties. Therefore, I can now confirm that all our third party agreements are fully	Following review of the supporting information submitted by the PR, The inspectorate considers this to be an acceptable response.

the HFEA CoP. (SLC T114 and T116)	CoP. Evidence of compliance to be forwarded to the lead inspector by 1 June 2012.	compliant.	
The centre's import and export SOP requires updating to include current references to the HFEA Directions. (SLC T33(b)).	The PR to ensure that the centre's import and export SOP is updated to include current references to the HFEA Directions. Evidence of compliance to be forwarded to the lead inspector by the time the PR responds to this report.	I can confirm that this SOP is updated to include the current references to the HFEA Directions.	Following review of the supporting information submitted by the PR, The inspectorate considers this to be an acceptable response.

Additional information from the Person Responsible
Finally, as Person Responsible, I can confirm that we have implemented all recommendations and addressed all areas of concern to ensure that we are fully compliant. We thank the inspection team again.

HFEA Executive Licence Panel Meeting

1 June 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0299 – (Centre for Reproduction and Advanced Technology) (CREATE) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Mark Bennett, Director of Finance & Facilities Paula Robinson, Head of Business Planning	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 this centre has been licensed since August 2008. The centre's current treatment and storage licence was granted on 1 August 2009 and will expire on 31 July 2012.

2. The Panel noted that at the time of the last inspection in April 2009 the centre occupied two separate sites; the main site housed the laboratory facilities where all the licensed activities took place and a second site was used for administrative purposes. Since then the administrative site has been closed and all functions have been transferred to the main site

3. The Panel noted that, based on data from November 2010 to October 2011, the centre's IVF and ICSI success rates are in line with national averages.

4. The Panel noted that at the time of the renewal inspection there were four major areas of non-compliance and two other areas of practice that required improvement.

5. The Panel noted that since the inspection the Person Responsible (PR) has provided evidence that three of the major non-compliances and the two other areas of practice that required improvement have been addressed. The PR has given a commitment that the one major area of non-compliance outstanding will be implemented within the specified timescales indicated in the report.

6. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions, subject to the implementation of the outstanding recommendations highlighted in the report within the prescribed time scales.

Decision

7. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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

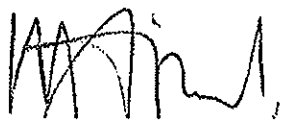
10. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

11. The Panel noted that the application does not involve the use of embryos for training purposes.

12. The Panel had regard 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 that the Executive Licensing Panel will normally grant a renewal licence for treatment/storage/non-medical fertility services licences for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

13. The Panel endorsed the recommendations made by the Inspectorate within the report, in particular the timely reporting of donor treatment cycles to the HFEA, as well as ensuring that the data submitted is accurate. The Panel endorsed the recommendation that the Inspectorate continue to monitor these areas.

14. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: 

Date: 20/06/2012

Juliet Tizzard (Chair)