# Inspection Report

**Date of Inspection:** 5 October 2011
**Purpose of inspection:** Interim inspection of treatment and storage licence
**Length of inspection:** 4.5 hours
**Inspectors:** Ellie Suthers, Lynne Nice

**Inspection details:**
The report covers the pre-inspection analysis, the visit and information received from the centre between 13 October 2009 and 4 November 2011

**Date of Executive Licensing Panel:** 18 November 2011

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

## Centre details

| | |
|---|---|
| **Centre name** | The Centre for Reproductive and Genetic Health |
| **Centre number** | 0044 |
| **Licence number** | L0044/15/L |
| **Centre address** | The New Wing, University College Hospital 256, Grays Inn Road, London, WC1X 8LD, UK |
| **Person Responsible** | Mr Paul Serhal |
| **Licence Holder** | Dr Joyce Harper |
| **Date licence issued** | 1/10/2009 |
| **Licence expiry date** | 31/03/2013 |
| **Additional conditions applied to this licence** | None |

# Contents

# Report to Executive Licensing Panel

## Brief description of the centre and its licensing history:

The Centre for Reproductive and Genetic Health is a purpose built facility within the Eastman Dental Hospital and has held a licence with the Human Fertilisation and Embryology Authority (HFEA) since 1990 with no additional licence conditions.

The centre offers a comprehensive range of assisted conception treatments to both NHS PCT commissioned and self-funded patients.

The centre provided approximately 1800 licensed treatment cycles per year and has one of the largest pre-implantation genetic diagnosis programmes in the UK.

## Activities of the Centre:

| Type of treatment | Number of treatment cycles for the period 1 July 2010-June 2011 |
|---|---|
| In Vitro Fertilisation (IVF) | 664 |
| Intra Cytoplasmic Sperm Injection (ICSI) | 432 |
| Frozen Embryo Transfer (FET) | 258 |
| Donor Insemination | 99 |
| Egg share provider (sharer) | 0 |
| Egg share recipient | 0 |
| Egg donation (non egg share) | 8 |
| Intra Uterine Insemination (IUI) | 526 |

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

## Outcomes*

For IVF/ICSI, HFEA held register data for the period April 2010 – March 2011 show the centres success rates are above the national averages in all treatments and age ranges.

For the year 2010 the centre reported 526 cycles of partner IUI with 52 pregnancies. This equates to an overall 9.8% pregnancy rate.

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

## Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that one area of major non-compliance which required improvement was identified in the course of the inspection.

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

**Major area of non-compliance:**

- The PR should ensure that all consent forms for the disclosure of information on the HFEA register are completed correctly.

  The PR should audit the consent to disclosure in the patient records against the consent decisions which have been submitted to the HFEA via EDI. This audit should encompass all patients for whom consent to disclosure has been submitted over the EDI system.

## Recommendation to the Executive Licensing Panel

The Inspection team recommends the continuation of the centre's licence without additional conditions subject to compliance with the recommendation made in this report being implemented within the prescribed timescale.

# Details of Inspection findings

## 1. Focus of inspections for 2010-12

**Providing information to patients in relation to costed treatment plans and parenthood**

What the centre does well.

**Costed treatment plans**
Before treatment, storage or both are offered, staff at the centre provide the person seeking treatment or storage, and their partner (if applicable) with a personalised costed treatment plan. The plan details the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The subject is discussed at the first consultation and an itemised list of proposed treatment and costs is provided to the patient. Four patient records were seen to contain detailed plans. Patient(s) interviewed at the time of inspection explained that they have had sufficient information about their treatment costs and had been afforded sufficient time to consider and discuss with staff. (Guidance 4.3)

**Parenthood**
Treatments with donor sperm and oocytes are provided to patients/partners who are married/in civil partnerships and to patients/partners who are not. A medical consultant demonstrated an understanding of the requirements for documenting parent and intended second parent consents and the requirements of Standard Licence Conditions T60, T61, T63, T64 and T65. Patient records reviewed at inspection contained legal parenthood information sheets and appropriately completed consent to legal parenthood consent forms.

The centres donor protocol includes a requirement to discuss with patients and partners the issue of the legal parenthood of a child born as a result of donation. This information includes the requirement for discussing the importance of informing any resulting child at an early age that they were born as a result of such treatment including suitable methods of informing such a child of that fact. Staff explained that the centre has a documented process to be followed in cases where the nominated second parent withdraws their consent to be treated as the parent of the child and that the woman receiving treatment would not be provided with treatment until she had been informed of this withdrawal of consent. (Standard Licence Conditions T64 and T65). Patient(s) interviewed at the time of inspection confirmed that this issue had been raised and discussed.

Information sheets on parenthood and requirements in SOP's are available to all members of staff via the centre's electronic document management system. (Standard Licence Condition T33b)

Staff at the centre have developed quality indicators that they audit monthly as part of the quality management system. (Standard Licence Condition T35 and T36)

What they could do better.

Nothing identified at this inspection

**Consent - particularly consent to disclosure to researchers and consent to storage**

What the centre does well.

Patients and their partners are asked to consent to the disclosure of their information held on the HFEA register to researchers as part of the consent taking process. (Guidance Note 5.27d)

Staff demonstrated an awareness and understanding of the compliance requirements related to disclosure of information on the HFEA register for use by researchers. HFEA consent forms and patient information sheets are accessible to all staff on the centre's electronic document management system and are provided to patients at initial consultation. Taking consent for the disclosure of information is detailed as part of the in the centres SOP for taking consent for treatments. (Standard Licence Condition T33b and guidance note 5 section 5.26)

An audit of five patient records demonstrated that written consent is in place for the storage of gametes and embryos. The documented consent also records the maximum storage period permissible and specifies the fate of the stored gametes and embryos in the event that the person(s) giving consent dies or is mentally incapacitated. (Guidance Note 5d)

An SOP describes the process to be followed if a patient (or partner) withdraws consent and the requirements of the 12 month "cooling off" period. (Guidance Note 5 H and 5.35)

What they could do better.

All five patients' records audited contained consent forms completed by both patient and partner, however, one consent form had not been completed correctly and in two instances the consent to disclosure to researchers in the patient record did not match the information held by HFEA. (Directions 0005, paragraphs 8 and 9 and standard licence condition T9 (e).

## Multiple births

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 17%.[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to meet the target for 2011/2012 at a statistically significant level, unlikely to be due to random variation.

What the centre does well

Ongoing monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (Standard Licence Condition 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 each year with a review and amendments as required each six months as part of the quality management audit programme;
- staff at the centre maintain a log of women receiving double embryo transfers who meet the criteria for single embryo transfer. The log details the reasons for multiple embryo transfer: Almost all were cited as patient request;
- Reasons for triple embryo transfer were cited as for women over the age of 40 with other indications such as previous treatment failures and poor embryo development.

Patients are informed of the centre's elective single embryo policy at the initial information session and this is also discussed at the first clinical consultation and with the embryologist during their patient journey up until the time of embryo transfer. Patient(s) interviewed at the time of inspection explained that the risks of multiple pregnancy and multiple births had been discussed prior to providing consent and treatment and that they had been provided with written and verbal information for consideration. An audit of the written patient information showed that all the requirements of guidance (Guidance 7.5 a, b, c and d) had been detailed. An audit of five patient records showed that patients are asked to sign a form to say that they have received the information and state the number of embryos they consent to be transferred.

Staff at the centre have developed quality indicators that they audit monthly as part of the quality management system. (Standard Licence Conditions T35 and T36)

What the centre could better

Nothing identified at this inspection.

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

## Validation of critical equipment and processes

What the centre does well.

Staff at the centre provided documented evidence showing that all critical equipment has been validated. (Standard Licence Condition T24) Detailed documents were provided for: an incubator, centrifuge, egg collection vacuum pump and IVF chamber. Staff maintain a log which records equipment maintenance history and repairs along with validation records. (Standard Licence Condition T25)

Documented evidence showed that instruments used for the procurement of gametes and embryos are validated and regularly maintained. Logs were provided for an incubator, centrifuge, egg collection vacuum pump and IVF chambers which record regular cleaning, maintenance, calibration and routine servicing. (Standard Licence Condition T28)

Staff provided documented evidence to show that all critical processes have been validated. It was also observed that all process SOP's have a completed process validation page with references as part of the document. (Standard Licence Condition T72)

What they could do better.

Nothing identified at this inspection

## Witnessing

What the centre does well.

Staff at the centre double check the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process ensuring that patients receive treatment using the correct gametes or embryos. (Standard Licence Condition T71)

An oocyte collection and semen preparation process was observed during the inspection. After positively identifying the patient, two members of staff witness the critical stages of the procedure at the time it is performed and a record is kept in the patient's record of the name, status and signature of both the person performing and the person witnessing the procedure. It was observed that the staff were following a SOP *Protocol for witnessing procedure LPo76.*
An audit of five patient records showed all critical points have been witnessed by two members of staff and documented appropriately.

Staff at the centre have developed quality indicators that they audit monthly as part of the quality management system. (Standard Licence Conditions T35 and T36)
Staff provided documented evidence of training and regular competency assessment as part of the appraisal process. (Standard Licence Conditions T15 and T36)

What they could do better.

Nothing identified at this inspection.

## Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Staff at the centre have processes and practices in place for gamete and embryo donation that are compliant with Directions 0001 and related Standard Licence Conditions detailed below.

The centre does not have an active donor recruitment programme; however, they do import sperm and eggs from overseas centres and infrequently facilitate the donation of embryos.

Two patients have chosen to offer their embryos for donation. Staff at the centre provided documented evidence to show that they follow a donor SOP and complete a donor checklist during the donation process. An audit of both sets of patient records showed that medical histories had been taken and documented; donor questionnaires had been completed and both patients/partners had undergone all the required donor screening investigations. (Standard Licence Condition T52) Documented evidence was provided to show that the screening is carried out in a Clinical Pathology Accreditation (CPA) (UK) accredited laboratory (Standard Licence Condition T53a). Both sets of embryos have been quarantined for 180 days and repeat testing carried out. (Standard Licence Condition T53c)

Documented evidence was provided to show that the embryo donors had received reimbursement restricted to expenses incurred in the UK within the limits prescribed in Directions 0001. Each donor record contained receipts to show that actual itemised expenses had been reimbursed.

Staff at the centre have SOPs and detailed checklists for the import of oocytes and sperm from overseas, largely from outside the EEA. The centre has a method of monitoring that the 10 family limit is not breached and act in accordance with the donors consent in relation to the number of families to be created. Staff provided documented evidence to show that they have checked that the donor has not received more than the prescribed amount of compensation or reimbursement (Directions 0001). Each donor record has an individualised letter from the donor centre confirming this.

Staff at the centre have developed quality indicators that they audit monthly as part of the quality management system. (Standard Licence Condition T35 and T36)

NB: In December 2010 the centre underwent an inspection in relation to oocyte importation from outside the EEA and found compliant with Directions 0006.

What they could do better.

Nothing identified at this inspection

## Embryo testing

What the centre does well.

Staff at the centre provided documented evidence that the biopsy procedures they use have been validated based on studies performed by the centre and from published studies. (Standard Licence Condition T72) A list of the validating references is attached to each SOP followed by staff. (Standard Licence Condition T33)

A laboratory log of biopsy procedures is maintained and is audited monthly to verify how far the biopsy procedures adhere to SOPs. (Standard Licence Condition T36) This is also used to assess staff competence as part of the annual appraisal process; evidence of which was seen in staff training logs. (Standard Licence Condition T15a)

Staff at the centre provided evidence to show that the laboratory that carries out the analysis/testing of the embryo biopsy is accredited by CPA UK Ltd. (Standard Licence Condition T21) and a third party agreement is in place between the centre and accredited laboratory. The third party agreement states that the laboratory will meet the requirements of the relevant licence conditions and guidance in the HFEA Code of Practice (8th Ed). (Standard Licence Condition T104)

Staff at the centre have developed quality indicators relating to embryo biopsy that they audit monthly as part of the quality management system. (Standard Licence Condition T35 and T36)

What they could do better.

Nothing identified at this inspection.

## 2. Changes / improvements since the previous inspection on 13 October 2009

| Area for improvement | Action required | Action taken as evidenced during this inspection |
|---|---|---|
| Adverse incident reporting: since the inspection in November 2007 there were 5 cases of severe OHSS and 1 other incident that had been recorded in the centres log book but were not reported to the HFEA<br>Section 17(1)g of the HFE Act (as amended)<br>Licence Condition T120<br>Directions 0011 | The PR should ensure that all adverse incidents and near misses including OHSS which require hospitalisation and has a severity grading of severe or critical are reported to the HFEA within the timeframes specified in Directions 0011 | All incidents of OHSS have been reported to the HFEA via the incident reporting route.<br><br>No further action required. |

## 3. 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 during the inspection visit to this centre.

| Area of concern | Inspection findings | Assessment of whether the findings meet the requirement or whether any further action is required |
|---|---|---|
| Is the laboratory that carries out the PGS and/or PGD accredited with CPA (UK) Ltd or an alternative body accrediting to the equivalent standards?<br>Standard Licence Condition T21<br>Centre self-assessment response NO | Evidence was provided at inspection to show that the laboratory is now accredited. | No further action is required |
| Does your centre have training and reference manuals?<br>Standard Licence Condition T33<br>Centre self-assessment response 2 | Training and reference manuals are available to all members of staff either in paper or electronically. | No further action is required |

# Areas of practice that require the attention of the Person Responsible

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

## Critical area of non-compliance

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

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| None identified at 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 |
|---|---|---|---|
| An audit of five patient records all contained consent forms completed by both patient and partners, however, one had not been completed properly and in two records the consent to disclosure to researchers in the patient records did not match the information held by HFEA<br><br>Standard Licence Condition T9 (e). Directions 0005, paragraphs 8 and 9 | The PR should ensure that all consent forms for the disclosure of information to researchers are completed correctly entered onto the HFEA register and completed accurately<br><br>Immediately<br><br>The PR should audit the consent to disclosure of information to researchers in the patient records against the consent decisions which have been submitted to the HFEA via the HFEA electronic data interface (EDI)<br>This audit should encompass all patients for whom consent to disclosure has been submitted over the EDI system.<br><br>The Executive recognises that this audit will be time consuming and recommends completion by January 1st 2012 and a report submitted to the Executive on the same date. | See comment from PR below. | |

| Area of practice and reference | Action required and timescale for action | PR Response | Executive Review |
|---|---|---|---|
| | The PR should ensure that in future, all data submitted through the EDI system regarding consent to disclosure of identifying information from the HFEA register is entered accurately. | | |

### 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 |
|---|---|---|---|
| None identified | | | |

## Additional information from the Person Responsible

Copied from email: 18/10/2011 19 06

Dear Ellie,

That is fine. We are happy with the rest of the report.

Best wishes,

Paul

**Mr Paul Serhal**
**Medical Director**
**Hon.Consultant/Lecturer**

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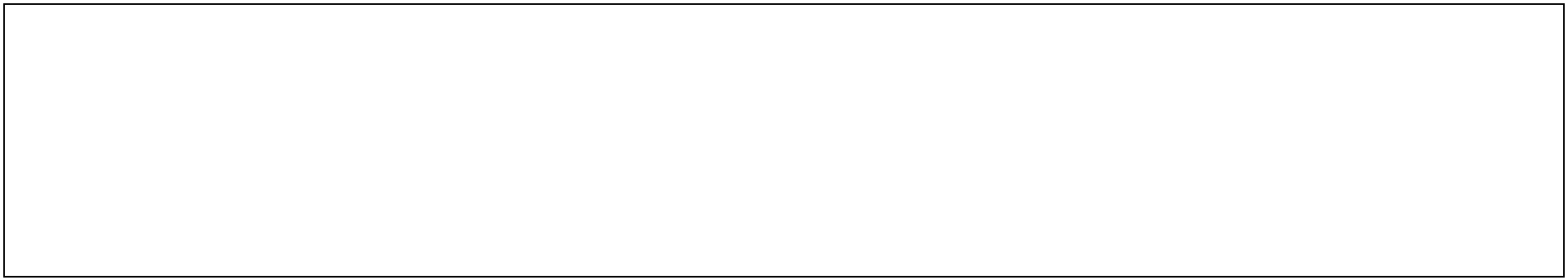

# HFEA Executive Licence Panel Meeting

**18 November 2011**

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

## Minutes – Item 1

**Centre 0044 – (Centre for Reproductive & Genetic Health) – Interim Inspection Report**

| Members of the Panel: | Committee Secretary: |
|---|---|
| Peter Thompson, Director of Strategy & Information (Chair)<br>Mark Bennett, Director of Finance & Facilities<br>Ian Peacock, Analyst Programmer | 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 treatment and storage centre has been operating since 1990, and offers a comprehensive range of assisted conception treatments to both NHS and self-funded patients.

2. The Panel noted that the centre provided approximately 1800 licensed treatment cycles per year and has one of the largest pre-implantation genetic diagnosis programmes in the United Kingdom.

3. The Panel noted that during the period of April 2010 – March 2011 the data held on the HFEA register shows that the centre's IVF/ICSI success rates were above the national averages in all treatments and age ranges.

4. The Panel noted that during 2010 the centre reported 526 cycles of partner IUI which resulted in 52 pregnancies. The Panel noted that this equated to an overall pregnancy rate of 9.8%.

5. The Panel noted that for the period 2010-11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%.

6. The Panel noted that at the time of the inspection one major area of non-compliance was identified. The action proposed by the Inspectorate required the Person Responsible (PR) to ensure that all consent forms for the disclosure of information on the HFEA register be completed correctly.

7. The Panel noted that since the inspection the PR has given a commitment to fully implement this one major area of noncompliance.

8. The Panel noted that non compliances identified in the previous inspection had now been addressed.

9. The Panel noted that the Inspectorate recommends the continuation of the centre's licence with no additional conditions, subject to the compliance with the recommendation made in the report being implemented within the prescribed timescale.

**Decision**

10. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Peter Thompson Date: 23/11/11.
Peter Thompson (Chair)