Interim Licensing Report

Centre name: **Reproductive Medicine Unit**

Centre number: **0167**

Date licence issued: **1 November 2008**

Licence expiry date: **31 October 2013**

Additional conditions of licence: **None**

Date of Inspection: **9 May 2012**

Inspectors: **Parvez Qureshi, Lynne Nice**

Date of Executive Licensing Panel: **10 August 2012**

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centres compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service:** the quality of service provided by a centre, including its success rates *and performance in reducing multiple births – the biggest single risk of IVF.*
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note: the positive comments made by patients in relation to their experiences.

The team has made recommendations for improvement and these should be implemented within the time specified.

There are recommendations relating to two **critical** areas of improvement and one **other** area of non-compliance as follows:

'Critical' areas of non compliance:

- **The PR should ensure that appropriate consent is obtained for the storage of all cryopreserved gametes.**
- **The PR should ensure that all gametes in storage are within the limit of the statutory storage period.**

'Major' areas of non compliance:

- None.

'Other' areas of practice that require improvement:

- The PR should ensure that staff competence to perform their designated tasks is documented.

Information about the centre

The Reproductive Medicine Unit is part of the University College London Hospitals NHS Foundation Trust and has held a licence with the HFEA since 1997.

The centre stopped providing donor insemination (DI) treatments in 2008 except for sibling treatment. Currently the centre provides basic partner services (intra uterine insemination (IUI) to National Health Service (NHS) patients and a sperm storage service for patients who have had treatment that may impair their fertility. The centre also provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health (0044).

The centre provided 359 IUI treatment cycles in 2011. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

For the year 2011 the centre reported 359 cycles of partner insemination with 35 pregnancies, this equates to a 10% pregnancy rate. The centre's success rates in terms of clinical pregnancy rates are in line with national averages.

Multiple births (SLC T123)

Not applicable to this centre.

Witnessing (SLC T71)

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error do not occur.

Sperm preparation activities were observed in the course of the inspection. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual witnessing system.

The inspection team was able to review records that were present in the laboratory and concluded that records of witnessing are maintained.

Consent : Disclosure to researchers (Direction 0007)

Not applicable to this centre.

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

Consent: To the storage of cryopreserved material (Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3, 2 (2))

A review of the centre's records of consent to storage of gametes showed that the centre does not have written effective consent for the storage of some cryopreserved gametes currently in store.

All material currently in storage was within the limit of the statutory storage period. However, there are historic samples in storage for oncology patients which pre date the HFE Act 1990. Currently these samples are being systematically audited and where possible patients are being contacted regarding on going storage of their samples (HF&E Act 1990 (as amended), Schedule 3, (8) (1) and 14(1)(c) – see recommendations 1 and 2).

Staffing (SLC T12)

Having the right numbers of staff, competent to carry out highly technical work in non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit the inspection team spoke to patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 17 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 13 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to the HFEA.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- The centre does not have written effective consent for the storage of some cryopreserved gametes currently in store and all material currently in storage is not within the limit of the statutory storage period (Act, Schedule 3, 8(1) and 14(1)(c).
- Not all staff were able to provide documented evidence of having demonstrated competence in their designated tasks (SLC T15(a) – see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in May 2010 recommendations for improvement were made in relation to six major non-compliances and one other area of non-compliance.

The PR supplied enough information and evidence within the required timescales to allow the inspector to assess that the centre is now compliant with those regulatory requirements and that no further action is required.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre submitted its annual IUI data for 2011 as required.

Annex 1

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 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	Inspection team's response to the PRs statement
1. The centre does not have written effective consent for the storage of some cryopreserved gametes currently in store. HF&E Act 1990 (as amended), Schedule 3, (8) (1)	The PR should ensure that appropriate consent is obtained for the storage of all cryopreserved gametes An action plan to be submitted to the lead inspector by the time the PR responds to this report.	We are aware of this area of non-compliance. A systematic review of all cryopreserved material is in progress. This was discussed at the Inspection. The protocol and monthly log of progress was submitted electronically to the lead inspector 1/06/2012.	Following review of the post inspection information submitted by the PR, The inspection team considers this to be an acceptable response and will be subject to on-going monitoring.
2. Not all material stored	The PR should ensure that all	We are aware of this area of non-compliance. A systematic	Following review of the post inspection information

	pre 1990 is within the limit of the statutory storage period. HF&E Act 1990 (as amended), Schedule 3, 14(1)(c).	gametes in storage are within the limit of the statutory storage period. An action plan to be submitted to the lead inspector by the time the PR responds to this report detailing the number of samples which are not within the limit of the statutory storage period.	review of all cryopreserved material is in progress, this includes the historic samples pre-dating the 1990 Act. This was discussed at the Inspection. The protocol and monthly log of progress was submitted electronically to the lead inspector 1/06/2012.	submitted by the PR, The inspection team considers this to be an acceptable response and will be subject to on-going monitoring.

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 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	Inspection team's response to the PRs statement
None identified at the time of this inspection.			

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	Inspection team's response to the PRs statement
3. Not all staff were able to provide documented evidence of the assessment of their competence to perform their designated tasks. SLC T15a	The PR should ensure that staff competence to perform their designated tasks is documented. This action should be implemented by 9 November 2012.	Since the inspection, we have designed checklists for staff induction, training, and annual competency assessment. These will be signed off by 9.11.2012.	The inspection team considers this to be an acceptable response and will be subject to on-going monitoring.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

10 August 2012

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

Minutes – Item 1

Centre 0167 – (Reproductive Medicine Unit) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Danielle Hamm, Senior Policy Manager David Moysen, Head of Information Technology	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 1997 and provides basic partner services (intra uterine insemination (IUI)) to NHS patients and a sperm storage service for patients who have had treatment that may impair their fertility.

2. The Panel noted that the centre also provides a satellite in vitro fertilisation (IVF) service to NHS patients for The Centre for Reproductive and Genetic Health (0044).

3. The Panel noted that in 2011 the centre provided 359 cycles of partner insemination with 35 pregnancies. This equates to a 10% pregnancy rate which is in line with national averages.

4. The Panel noted that at the time of the inspection the Inspectorate identified two critical areas of non-compliance and one other area of practice that required improvement.

5. The Panel noted that the two critical areas of non-compliance related to the centre not having written effective consent for the storage of some cryopreserved gametes currently in store, although storage is within the limit of the statutory storage period (HFE Act, Schedule 3, 8(1) and 14(1)(c). The other area of non-compliance related to documented evidence of staff having demonstrated competence in their designated tasks.

6. The Panel noted that the Inspectorate is satisfied with the Person Responsible's response to all recommendations in the report and that some of these areas are subject to on-going monitoring.

7. The Panel noted that following the previous inspection visit in May 2010, recommendations for improvement were made in relation to six major non-compliances and one other area of poor practice. The Panel noted that these areas have now been implemented to the satisfaction of the Inspectorate.

8. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions.

9. The Panel noted the progress that has been made at the centre since the last inspection, and encouraged the PR to continue to work with the Inspectorate.

Decision

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

Signed:  Date: 20/8/12

Juliet Tizzard (Chair)