Interim Inspection Report

Date of Inspection: 12 May 2010
Length of inspection: 6 hours
Inspectors Parvez Qureshi
Lynne Nice (External Adviser)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between November 2008 and 10 September 2010

Date of Licence Committee: 10 September 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence 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 Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Reproductive Medicine Unit
Centre Number	0167
Licence Number	L0167-10-B
Centre Address	University College London Hospitals Elizabeth Garrett Anderson Wing 235 Euston Road London NW1 2BU
Telephone Number	020 7380 9697
Person Responsible	Mr Rehan Salim
Licence Holder	Professor David Fish
Date Licence issued	1 November 2008
Licence expiry date	31 October 2013
Additional conditions applied to this licence	None

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Report to Licence Committee / Executive Licensing Panel

Recommendation to the Licence Committee / Executive Licensing Panel:

The inspectorate considers that overall there is sufficient information on which to recommend the continuation of the centre's licence without additional conditions.

The inspectorate also recommends that the Executive Licensing Panel requires that the Person Responsible (PR) complies with the following recommendations within the prescribed timeframes set out in the inspection report:

1. The PR should ensure competency assessments for all staff are conducted and documented

2. The PR should ensure all critical processing procedures are validated

3. The PR should ensure that all critical equipment and technical devices are identified and validated

4. The PR should ensure that procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure

5. The PR should ensure that a procedure for monitoring of equipment that affects processing or storage of materials is established

6. The PR to risk assess or review practice in order to ensure that no unauthorised access is possible to the premises

7. The PR must report storage of oncology samples without consent as an incident to the HFEA

Since the inspection, the PR has provided an update on actions taken in response to the recommendations cited above. The inspectorate considers the actions to be a suitable response.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Reproductive Medicine Unit has been licensed since 1997 and is part of the University College London Hospitals NHS Foundation Trust. The centre relocated to a new site in November 2008 and provides treatment to National Health Service (NHS) patients from a wide geographical area.

The centre stopped providing donor insemination (DI) treatments in 2008 except for patients requiring sibling treatment. Data submitted by the centre to the HFEA indicate the centre provided 487 intra uterine insemination (IUI) treatment cycles in 2009 with success rates in line with the national averages.

The centre also provides a sperm storage service for patients who have had treatment that may impair their fertility. A satellite in vitro fertilisation (IVF) service in conjunction with The Centre for Reproductive and Genetic Health (0044) is in place.

Since the last inspection in August 2008, no major changes have been made to the premises other than rearrangement of the administration and consulting areas. Opening hours at the centre are Monday - Friday 9am - 5pm.

A variation of the centre's licence to change the Person Responsible (PR) from Mr Ertan Saridogan to Mr Rehan Salim was granted by an Executive Licensing Panel in May 2009. The new PR is a consultant gynaecologist and obstetrician and is registered with the General Medical Council (GMC). He is also a member of the Royal College of Obstetricians and Gynaecologists (RCOG).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 January 2009 – 31 December 2009
Intra uterine insemination	487

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

*These data were extracted from the HFEA register for the period 1 January 2008 – 31 December 2009. 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.

1. Focus of inspections for 2010-12

Witnessing
Evidence of how the centre demonstrates compliance with the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. A Standard Operating Procedure(SOP) for witnessing is 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. An audit of five sets of patients' notes was found to contain a record of the witnessing checks of the person performing the procedure and of the person witnessing the procedure. These records included the respective names, signatures and status. The centre has established quality indicators relevant to witnessing and it has audited against compliance with the approved protocols, the regulatory requirements and quality indicators. Evidence of this was made available for the inspection team.
What the centre does well. Audit of quality indicators relevant to witnessing.
What they could do better. All staff involved in conducting witnessing were not able to provide documented evidence of their competency in carrying out witnessing. PR should ensure that the competency for all staff is documented in compliance with T15(a).

Parenthood
Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood Not relevant for this centre as it no longer provides treatment with donor sperm.
What the centre does well. N/A
What they could do better. N/A

Information about the cost of treatment
Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients Not relevant for a centre which provides only NHS treatment.
What the centre does well. N/A
What they could do better. N/A

Patient consent to the disclosure of information, held on the HFEA Register, for use in Research
Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research. This criterion is no longer relevant to this centre.
What the centre does well. N/A
What they could do better. N/A

Consent issues in relation to the storage of embryos (including cooling off period)
Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment. This criterion is not relevant to this centre.
What the centre does well. N/A
What they could do better. N/A

2. Changes / improvements since the last inspection on 28 November 2008

Area for improvement	Action required	Action taken as evidenced during this inspection
The average time for the payment of treatment fees to the Authority is 71 days. This is a breach of Standard licence condition A.13.3 which states that the Person Responsible agrees that s/he will pay to the Authority any additional fees, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	Since the last inspection, the centre has put a system in place with the Trust Finance Department to ensure all treatment fees are paid to the HFEA within the required timeframe. At the time of inspection it was noted that the centre had only one recent outstanding invoice to clear. The PR stated that this would be addressed.
Air quality in the environment in which gametes are processed has not been demonstrated to meet the required standards. A.10.19 G.9.4.5 Code of Practice 7th (CoP) 7th **Guidance Note 25 (8th Ed)**	The processing of gametes while exposed to the environment should take place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality as required by standard license condition A.10.19. The PR should ensure that where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result. in compliance with G.9.4.5.	All sperm preparations are carried out in class II laminar flow cabinets. Currently air quality is measured on an annual basis A review of data for annual air quality testing carried out in 2008 and 2009 indicated Grade C air quality within the laminar flow cabinets with a background environment of Grade D.
Continuing education and professional development (CPD) for laboratory staff is	Laboratory staff should maintain their CPD and this training should be	Evidence of availability of CPD for all staff was seen during the course of the

not maintained. S.6.2.11. and A.10.11 CoP) 7th **Guidance Note 2 (8th Ed)**	documented and monitored In compliance with S.6.2.11. and A.10.11 .	inspection. All new members of staff undergo an induction programme. Mandatory training for staff is supplied by the Trust.
Issues from New Premises Site Visit Report of 28 August 2008 **Guidance Note 26 (8th Ed)**	To perform a risk assessment for the safe transfer of the dewars prior to move. Establish air quality when equipment and staff in facility under working conditions. Develop a protocol of how often air quality is monitored. Ensure logs of parameters related to the performance of key equipment are kept including SOPs. Key equipment will need to be re-calibrated and validated prior to the commencement of service.	Evidence of this was provided at the time of move to the new premises and was considered to be acceptable. Evidence of this was provided at the time of move to the new premises and was considered to be acceptable. Currently the air quality in the laboratory is measured on an annual basis. However, there is no protocol in place for how frequently the air quality should be monitored. The inspection team noted that current logs of parameters related to the performance of all critical equipment and SOP's were not in place. The PR stated that only one centrifuge was transferred from the previous premises and it was re-calibrated prior to commencement of service.

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 action taken meets requirement or whether any further action is required
Competency assessment for all staff. **Guidance Note 2 (CoP 8th Ed)**	The PR stated that, since the last inspection in August 2008, assessment of competency of laboratory staff in the course of the provision of training by personnel from centre 0044. Evidence of this was not made available for the inspection team which meant that at the time of the inspection not all staff were able to provide documented evidence of the assessment of their competence in the performance of their designated tasks.	While the PR has provided reassurance that competence has been assessed the PR should ensure that the competency for all staff is documented in compliance with T15(a). The PR should provide written confirmation to the HFEA that this has been completed with evidence to be reviewed at the time of the next inspection.
The documentation of the findings of audits and any corrective actions. **Guidance Note 4 (CoP 8th Ed)** **Guidance Note 5 (CoP 8th Ed)**	The members of staff who met with the inspection team stated that findings of all audits and any relevant actions are documented. Evidence of this was made available for the audits of patient notes and complaints.	No further action is required.
To verify whether consent is ever obtained on the day that a procedure occurs. **Guidance Note 5 (CoP 8th Ed)**	The PR stated that consent is obtained prior to any treatment. However, for oncology patients consent for storage of sperm can take place on the day the sample is produced. While this may be a concern where patients have an opportunity to provide consent well in advance of treatment (thus ensuring that patients have an adequate opportunity to consider the implications of their decision) in	No further action is required.

	circumstances where a patients may need to store their gametes without delay, this is considered an acceptable procedure.	
The establishment of quality indicators or objectives relevant to the assessment of the welfare of the child? **Guidance Note 5 (CoP 8th Ed)**	Evidence of assessment of WoC being conducted by the centre was seen in the patients notes. Quality indicators relevant to WoC and for a number of other areas of practice including consent and provision of information were seen in the patient notes.	No further action is required.
Verification that all material currently in storage was within the limit of the statutory storage period. **Guidance Note 17 (CoP 8th Ed)**	The PR stated that all material currently in storage was within the limit of the statutory storage period. However, there are historical samples in storage for oncology patients which pre date the HFE Act 1990. Currently all stored samples at the centre are being audited and where possible patients are being contacted regarding on going storage of their samples. The PR anticipates this process will be completed within the next year. Samples stored prior to the implementation of the Act are not subject to the requirements of the Act. Subsequent to the inspection the centre has reported to the HFEA that they have identified a number of oncology samples in storage (post HFE Act 1990) without written consent. Currently all stored samples at the centre are being audited and the centre anticipates finding further samples in store without written consent in place. Schedule 3, S. 8 (1) of the Act states that a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent. Schedule 3, S.	No further action is required. The PR was asked to treat and report this to the HFEA as an incident.

	1 states that a consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing. In storing gametes without written consent, the centre is in breach of these requirements.	
Validation of critical processes. **Guidance Note 17 (CoP 8th Ed)**	No documented evidence was provided by the centre for validation of processes including procedures for storage of sperm.	The centre should validate all processes, including those used for air quality monitoring, based on studies performed by the centre itself or on data from published studies or from well established procedures in compliance with T72.
Validation of critical equipment.	No evidence was made available for validation of laboratory equipment.	The centre should validate all critical equipment in compliance with T24. It is recommended that the centre provide a timeline documenting all critical equipment and the timeframe for completion of the validation process. The timeline should be submitted by 12 July with quarterly updates documenting progress to be submitted on a quarterly basis.
Malfunction of equipment.	The centre has standard operating procedures in place for the operation of the laboratory equipment. However, there is no documented procedure in place which outlines the process to follow in the event of malfunction or failure of equipment.	The laboratory staff should develop an SOP for actions to be taken in event of malfunction or failure of equipment in compliance with T27.

Monitoring of equipment that affects processing or storage of materials. **Guidance Note 26 (CoP 8th Ed)**	The inspection team noted that currently the centre does not have a process in place for monitoring of all equipment with critical measuring function including the fridge located in the laboratory.	The PR should ensure that equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. In compliance with T24.
Access to premises. **Guidance Note 25(CoP 8th Ed**	Overall there is controlled access to the premises. However, the clinical facilities are shared by a number of other services provided by the hospital. The inspection team noted an unattended trolley containing a number of patient notes situated in the corridor opposite to the reception.	The PR should ensure that patient confidentiality is not compromised by any unauthorised access to patient records. It is recommended that an audit of compliance with requirements related to the maintenance of patient confidentiality is carried out by 12 July and that the report of the findings and any corrective actions are provided to the HFEA.

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None identified at the time of this inspection.					

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Staff Competencies for all staff need to be assessed and documented.	Standard licence condition T15a CoP Guidance Note 2.1b	Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual has demonstrated competence in the performance of their designated task. Competencies should be assessed on an on-going basis.	An action plan for completion to be submitted by the time PR responds to this report.	At the time of the inspection, all staff had started the process of competency assessment and relevant professional development. This program is ongoing and we anticipate that documentary evidence for all relevant areas of practice will be in place within the next three months. We then plan to reassess on an annual basis.	The inspectorate considers this to be an acceptable response. To be reviewed at the time of the next inspection.
Storage of gametes and embryos The centre has not validated critical processing procedures.	Standard licence condition T72 CoP Guidance Note 17	The PR should validate all critical processing procedures. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results	This has been a requirement of the Act since July 2007 and in recognition of this it is recommended that the centre provide a timeline documenting all critical processing	A protocol for validating critical laboratory processing procedures is in place and completed (submitted to HFEA)	The inspectorate considers this to be an acceptable response. Progress to be monitored at the time of

		of tissues provided by the establishment.	procedures and the timeframe for completion of the validation process. The timeline should be submitted by 12 July with updates documenting progress to be submitted on a quarterly basis Professional body guidelines on validation have been drafted by the Association of Clinical Embryologists		next inspection.
Equipment and materials The centre has not validated all critical equipment.	Standard licence condition T24 CoP Guidance Note 26	The PR should ensure that all critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate	This has been a requirement of the Act since July 2007 and in recognition of this it is recommended that the centre provide a timeline documenting all critical procedures and the timeframe for completion of the validation process. The timeline should be submitted by 12 July with updates	A timeline is now in place and we anticipate completion within the next twelve months (submitted to HFEA	The inspectorate considers this to be an acceptable response. Progress to be monitored at the time of next inspection

		monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.	documenting progress to be submitted on a quarterly basis. Professional body guidelines on validation have been drafted by the Association of Clinical Embryologists		
An SOP for all actions to be taken in the event of malfunction or failure of equipment not in place.	Standard licence condition T27 CoP Guidance Note 26	The PR should ensure that procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.	By the time PR responds to this report.	This has been completed	The inspectorate considers this to be an acceptable response.

Monitoring of equipment that affects processing or storage of materials.	Standard licence condition T24 Guidance Note 26	Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.	To be monitored at the time of the next inspection.	A protocol has been set up to monitor all equipment and to ensure that these operate within the set parameters (submitted to HFEA).	The inspectorate considers this to be an acceptable response. To be monitored at the time of next inspection.
Consent Storage of oncology samples without effective consent.	The HFE act 1990 (as amended) Schedule 3, 8(1)	The PR was asked to treat and report this to the HFEA as an incident.	Immediately.	Completed.	An incident report was submitted by the PR to the HFEA.

Other areas of practice that requires improvement

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Premises and facilities – Access to the premises should be assessed.	Guidance Note 25	The PR should conduct an audit of compliance with requirements related to the maintenance of patient confidentiality.	By 12 July and that the report of the findings, and any corrective actions are provided to the HFEA.	This has been completed and the premises have no current or potential issues that would lead to a compromise in patient confidentiality.	The inspectorate considers this to be an acceptable response.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

10 September 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0167 (Reproductive Medicine Unit, UCLH) - Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Hannah Darby, Policy Manager	Terence Dourado

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

- Interim inspection report
- Minutes of Licence Committee:
- Change of PR (6 May 2010)
- Interim inspection (27 October 2008)
- Change of premises (15 October 2008)
- Renewal of licence (15 August 2007)

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 Directions 0000 – 0012

- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Centre has been licensed since 1997 and moved to a new site in November 2008. The Centre provided 487 intra uterine insemination (IUI) treatment cycles in 2009 with success rates in line with national averages.

2. The Panel noted that the Person Responsible (PR) is a Consultant gynaecologist and obstetrician and is registered with the General Medical Council (GMC). He is also a member of the Royal College of Obstetricians and Gynaecologists (RCOG).

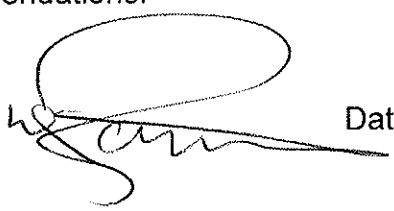
3. The Panel considered the Interim Inspection Report and was satisfied that the Centre is compliant. It was satisfied that the Inspector has received assurances from the PR that any outstanding recommendations will be implemented.

4. The Panel was satisfied that embryos being stored without consent had been addressed by the centre, and noted that it has now reported this as an incident to the HFEA.

5. The Panel noted that the self assessment questionnaire seemed open, honest and realistic.

Decision

6. The Panel agreed to the continuation of the Centre's licence without any conditions placed upon it. The Panel endorsed the Inspectorate's recommendations and the associated timeframes for the PR to meet these recommendations.

Signed:  Date: 21/9/10

Mark Bennett (Chair)