Renewal Inspection Report

UCH London
0044

Date of Inspection: 6th November 2007
Date of Licence Committee: 28th January 2008

CENTRE DETAILS

Centre Address	The New Wing Eastman Dental Hospital 256 Gray's Inn Rd London WC1X 1LD
Telephone Number	0207 837 2905
Type of Inspection	Renewal
Person Responsible	Mr Paul Serhal
Nominal Licensee	Dr Joyce Harper
Licence Number	L0044-14-b
Inspector(s)	Wil Lenton (Chair, HFEA) Gill Walsh (HFEA) Parvez Qureshi (HFEA)
Fee Paid - date	Not yet
Licence expiry date	31 March 2008

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About the Inspection:
This inspection visit was carried out on 6th November 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 01/01/06 and 31/12/06.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the 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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Assisted Conception Unit has been licensed by the HFEA since 1990. The majority of patients who attend the centre are from London and the surrounding area and are self-funded. The unit provides over 650 licensed treatment cycles per year and is one of the largest PGD/PGS services in the country. The Person Responsible (PR) has completed the PR Entry Programme and is appropriately qualified and experienced to discharge his duties.

In November 2005 the centre moved to its present premises in the Eastman Dental Hospital. It has been ISO-9001/2000 accredited since April 2007 and has a robust quality management system in place. Their licence was varied recently to accommodate the requirements of the EU Tissues and Cells Directive (EUTD) with a low risk score of 3%

Fertility treatments are provided between 0900 and 1700 five days a week and if necessary patients are also seen at weekends.

Activities of the Centre (HFEA Registry 01/01/06 to 31/12/06)

Licensed treatment cycles	Egg Donor	26
	Egg Recipient	15
	IVF	269
	ICSI	203
	FET	104
	DI	44
Unlicensed treatments	Ovulation Induction	
Research	Yes	
Storage	Yes	

Summary for Licence Committee

The centre was found to be cohesive and well organised, with a good QMS in place which underpinned the clinical service. There were adequate numbers of qualified and trained staff in post to deliver the services provided.
During the course of the visit a number of regulatory issues were identified and are summarised below;

- During the last cryotank audit it was found that four patients samples were being stored past their storage consent expiry date

- Some amendments to the laboratory witnessing SOP's were required

The weight to be attached to these regulatory issues is a matter for the Licence Committee to determine

The inspection team supports the renewal of the centre's treatment and storage licence for five years with no additional conditions.

Risk Assessment

Following the inspection, the risk assessment as calculated via the HFEA Risk Tool is low at 5%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation	X		
2. Quality of the service		X	
3. Premises and Equipment	X		
4. Information	X		
5. Laboratory and clinical processes		X	

Breaches of the Act or Code of Practice

The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice. The weight to be given to any breaches of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee.

Breach	Action required	Time scale
Patient's sperm samples kept past storage consent expiry date. *(CoP7 – S.7.8.11)*	Adherence to CoP7	Immediately

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
Laboratory witnessing SOP's to be amended/updated.	3 months

Proposed licence variations

None

Changes/ improvements since last inspection (April 2006)

Recommendation	Action taken
Splitting of oncology sperm samples.	Completed 2006.
Improvement to the standard of information provided by the centre.	All patient information has been updated.
The counsellor to be better informed of centre activities/meetings.	All staff now made aware of forthcoming meetings and minutes taken.

Additional licence conditions and actions taken by centre since last inspection

C	None

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

1. General organisation of the centre
2. Quality management system
3. Continual improvement
4. Corrective action
5. Preventive action
6. Internal audit
7. Establishment and review of contracts with third parties and transport
8. Transportation, labelling of shipping container and recall
9. Incident Reporting
10. Alerts
11. Notification of serious adverse reactions
12. Equality and Diversity
13. Risk Management
14. Donors
15. External reviews
16. Contingency arrangements

Areas of firm compliance
An organisational chart was provided as part of the pre-inspection information, which detailed the centre's lines of communication and reporting structure. A staff list was produced on the day of the inspection, which together with the organisational chart appeared to show that the centre had adequate numbers of qualified/trained staff with which to deliver the range of patient services provided. The centre has been ISO-accredited since April 2007 and it was evident during the inspection that this quality management system (QMS) underpinned the centre's activities/services. An SOP for the induction of new staff was seen and staff interviewed on the day were able to discuss issues such as patient confidentiality, welfare of the child, privacy and respect. Individual training logs are kept by each staff member and were observed to be up-to-date. CPD logs were also made available. Recently the Senior Embryologist had spent time with a unit in Japan in order to develop a vitrification technique for the unit. Annual appraisals are performed by the relevant line-manager and competencies reviewed by monitoring individual outcomes. (ICSI; ET's) Evidence of regular minuted meetings was observed for individual discipline groups (administration, clinical, embryology, and nursing) as well as all-staff unit meetings. Alerts are circulated to all staff and signed-off as read. A hard file is kept by the unit manager.

Both a database and hard-log of third party agreements were evidenced during the inspection.

Incidents are reported to the HFEA and an incident log was seen on the day of the visit.

A contingency agreement is in place with the London's Women Clinic (centre 0105)

Areas for improvement
None

Minor issues to be addressed
None

Areas not covered on this inspection
None

Evaluation
No improvements required

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

1. Live Birth Rates
2. Confidentiality and access to health records
3. Needs and requirements of users
4. Assessment of user satisfaction
5. Quality objectives and plans
6. Quality Manager
7. Quality Review
8. Counselling
9. Welfare of the Child
10. Monitoring and resolutions of complaints
11. Staff suggestions
12. Patient choice
13. Egg Sharing and Surrogacy

Live Birth Rates (HFEA validated data)
• ICSI/IVF success rate for age group 'below 35' significantly higher than the National Average • FET success rate for age group 'below 35' higher than the National Average • DI success rate for age group 'below 35' similar to the National Average
Areas of firm compliance
The success rates for this centre are generally very good across all age groups. The PR explained that all female patients are carefully assessed and individualised treatment protocols devised, in order to maximise their chance of success. A quality manager is in place and a robust QMS underpins the clinical services provided. From analysis of the returned HFEA patient satisfaction questionnaires the majority of respondents described a positive experience when visiting the centre. A complaints log was seen during the visit, with all complaints shown as resolved. The centre has access to an independent counsellor, who is a member of BICA and who is available to patients via appointment. The counselling sessions take place off-site and notes are kept separate and secure. The counsellor is appropriately qualified/trained to provide this service and attends regular supervision with a mentor. A counselling audit was supplied with the pre-inspection documentation, the results of which are summarised as;

Total sessions = 135
Total clients seen = 133

Implications Counselling (68)
Egg recipient = 24
Egg donor = 21
Sperm recipients = 15
Sperm donors = 8

Therapeutic Counselling = 17
Couple Counselling = 5
Support Counselling = 42

Areas for improvement

The uptake of counselling services at the centre was regarded to be lower than average for the unit's size.

Minor issues to be addressed

None

Areas not covered on this inspection

None

Evaluation

Some improvements required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

1. Any Changes
2. Suitable premises
3. Safe working with environment
4. Clinical facilities
5. Counselling facilities
6. Laboratory facilities
7. Storage facilities for gametes and embryos
8. Air quality
9. Staff facilities
10. Suitable equipment
11. Management of equipment and materials
12. Alarms
13. O2 alarms
14. Handling and manipulation of gametes and embryos
15. Dewars

Areas of firm compliance
During an initial tour of the centre by the inspection team, the premises and facilities were found to be clean and fit for purpose. All cryo-dewars at the centre were seen to be secure and fitted with low liquid nitrogen alarms connected to an auto-dialler system for out-of-hours incidents. A written protocol was in place to cover such situations. A low Oxygen monitor was in place within the cryostorage area, with an external audio/visual alarm. Air quality is being monitored within the laboratory and the latest results were viewed and found to be within required limits as stipulated under the EUTD. Equipment service/maintenance logs were reviewed during the inspection and found to be up-to-date in all areas. All patient-sensitive areas were seen to be secure with restricted staff access.
Areas for improvement
None
Minor issues to be addressed
None

Areas not covered on this inspection

None

Evaluation

None.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

1. Meetings and communication
2. Information management
3. Quality manual
4. Document control
5. Control of Records
6. Donor registration
7. Receipt of gametes
8. Home Procurement documentation
9. Traceability
10. Material donated to research
11. Coding
12. Information for users This section includes: Access to data
13. Tracking live birth events
14. Storage records
15. Information to the HFEA
16. Counsellor records
17. Import/export
18. 3 embryo transfer
19. Donor Information
20. Storage and release of gametes and embryos
21. Storage forms
22. Anonymity
23. Labelling of packages containing procured gametes
24. Validations
25. Screening
26. Audit
27. Consents

Outcome of audit of records
Five sets of notes were reviewed during the inspection and found to be in good order.
Areas of firm compliance
HFEA licence, ISO accreditation, HCC and employers liability insurance certificates were prominently displayed within the main waiting area, together with details on the centre's complaints procedure. All patient information reviewed was clear and accurate and is held within the centre's QMS. This documentation is regularly reviewed and updated to reflect changing professional guidelines, patient feedback and/or HFEA alerts. All staff have access to this information via the secure IT network. Only named individuals can authorise the updating of patient

information and/or centre protocols in keeping with the QMS document control policy.

Current patients' records were seen to be securely stored in an appropriate file-room. Any records which were inactive for two years or more were removed to an off-site store.

A written home-procurement protocol was seen to be in place for male partners who needed/requested to produce their samples at home.

A 3-embryo transfer log was reviewed. All cases seen were in well documented cases of women >40 years, who had multiple, previous failed attempts and/or poor embryo quality.

Areas for improvement
None

Minor issues to be addressed
None

Areas not covered on this inspection
Validation

Evaluation
No improvements required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Staffing Personnel Records
2. Criminal convictions
3. Initial /basic training and update training
4. Competence
5. Annual joint review
6. Continuing education and professional development
7. Procedures
8. Clinical Processes
9. Clinical treatment
10. Procurement, Distribution (including packaging and transportation), and receipt of gametes and embryos
11. Viral positive patients
12. Cross infection
13. Laboratory Processes
14. Selection and Validation of laboratory procedures
15. Screening
16. Emergency procedures
17. Handling and manipulation of gametes and embryos
18. Witnessing
19. Assuring the Quality of procedures
20. Participation in inter-Centre comparisons and inter-Laboratory comparisons

Full time equivalent staff

GMC registered doctors	7
NMC registered nurses	9
HPC registered scientists	3
Scientists working towards registration	3
Support staff (receptionists, record managers, quality and risk managers etc)	9

Summary of laboratory audit
1. Sperm storage: • physical audit of tanks carried out during October 2006 • corresponding audit of freeze paperwork completed February 2007 • 4 patients samples stored after consent expiry date 2. Embryo storage: • physical audit of tanks carried out during May 2006 • corresponding audit of freeze paperwork also completed May 2006 • No discrepancies found An embryo tank audit is presently underway.

Summary of spot check of stored material
1 sperm sample was tracked from database to tank and vice versa 1 embryo sample was tracked from tank to database and vice versa No discrepancies were found
Areas of firm compliance
All new laboratory staff follow a centre-specific induction course and sign a confidentiality agreement when in post. Laboratory training logs were seen to be up-to-date. Staff CPD included attendance at ACU journal clubs, research meetings, as well as local, national and international meetings/conferences (HFEA, BFS, ESHRE etc) The laboratory has restricted staff access and was observed to be kept secure during the inspection. Laboratory equipment such as incubators/heated surfaces/blocks are monitored and parameters such as temperature and $\%CO_2$ recorded regularly in a hard-log as part of a quality control policy. A spreadsheet was seen giving details of equipment servicing/maintenance, which was up-to-date. Laboratory outcomes (KPI's) are monitored on a regular basis, discussed at monthly, minuted, audit meetings and form part of the QMS audit. The centre follows a written witnessing SOP, when handling gametes/embryos and has a checklist when accepting/transferring gametes/embryo's to other licensed centre's. The laboratory has a system in place for recording all media, laboratory consumables and equipment used when processing gametes/embryo's. Air quality is checked within the laminar flowhoods as part of the regular service contract and an independent company is used to check background air quality. No viral positive patients are treated.
Areas for improvement
Expiry of storage consent for four sperm storage patients. The laboratory witnessing SOP's require review/amendment. • embryo's donated to research • freezing/thawing of embryo's • SOP to be written to complement checklist for acceptance/transfer of gametes/embryo's to another licensed centre. • amendments to existing SOP for transportation of gametes/embryo's to another licensed centre
Minor issues to be addressed
None

Areas not covered on this inspection

None

Evaluation

Some improvements required.

Report compiled by:

Name…… Wil Lenton……

Designation……HFEA Inspector……..

Date……11/12/07……

Appendix A: Centre Staff interviewed

The PR plus five other members of staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 5th December 2007
Variation of licence to include PGD for Familial Hypercholesterolaemia

Licence Committee 13th September 2007
Variation of licence to include PGD for BRCA1

Licence Committee 9th July 2007
Variation of licence to include PGD for BRCA1

Licence Committee 2nd May 2007
Variation of licence to include requirements of the EUTD

2006

Licence Committee29th November 2006
Variation of licence to include PGD for Coffin-Lowry syndrome

Licence Committee22nd November 2006
Variation of licence to include PGD for Von Hippel Lindau syndrome

Licence Committee 16th August 2006
Variation of licence to include PGD for HLA Beta Thalassaemia

Interim Inspection 11th April 2006

2005

Post-change of Premises Inspection 12th December 2006

Licence Committee 12st October 2005-Change of Premises
The Committee agreed to the change of premises.

Pre-change of Premises Inspection 16th September 2005

Licence Committee 12st January 2005– Renewal Inspection
The Committee noted there were no additional conditions on the centre's licence agreed to add three recommendations.

2004

Renewal Inspection 28th October 2004

Licence Committee 15th September 2004
The licence committee agreed to split off the responsibility for the research project R0113 to a new centre [0245 Human Genetics & Embryology Laboratories]. There was no physical change to the location of the project.

Licence Committee 13th May 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD)

for a complex translation. [AP-03-0068]

Licence Committee 22nd April 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD) for three β thalassaemia mutations. [AP-04-0049]

Licence Committee 5th April 2004
The committee agreed to vary the licence to include pre-implantation genetic diagnosis (PGD) for four β thalassaemia mutations. [AP-04-0049]

Licence Committee 28th January
The committee agreed in principal to include PGD for a complex translocation [AP-03-0068] further clarification was sought. See Licence Committee 13/05/2004.

Licence Committee 21st January – Interim Inspection
The Committee noted there were no additional conditions on the centre's licence agreed to add two recommendations.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…0044

Name of PR…Mr Paul Serhal

Date of Inspection… 6th November 2007

Date of Response… 12th December 2007

Please state any actions you have taken or are planning to take following the inspection with time scales

We have read the draft inspection report and we are satisfied with the content. We confirm that we have now implemented a system to contact the patients three months before consent expiry followed by two letters at a monthly interval before discarding
the samples.

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

28 January 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

UCH London (0044)
Licence Renewal

Members of the Committee:

Jennifer Hunt, Lay Member – Chair
David Archard, Lay Member
Sally Cheshire, Lay Member
Hossam Abdalla, Director of Lister Fertility Centre

Present via teleconference phone:
Neva Haites, Professor of Medical Genetics, University of Aberdeen

In Attendance:

Stephanie Sullivan, Interim Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Stephen Hocking, Beachcroft LLP Solicitors

Observing:
Ellie Suthers and Carol Horner, HFEA Inspectors
Simon Achonu, Beachcroft LLP (trainee)

Conflicts of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item. However, Hossam Abdalla asked it to be noted that he was Director at another London based fertility centre.

Stephen Hocking reported that his firm acted for UCLH, although not on any matter relevant to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (38 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this centre has been licensed since 1990 and carries out about 650 treatment cycles per year, mainly for self-funded patients. The centre has an extensive programme of PGD treatments and has been ISO accredited since April 2007.

2. Mr Lenton summarised the findings of the inspection report drew the Committee's attention to the breach of the Code of Practice and the recommendation by the inspection team. Mr Lenton also informed the Committee that a response has been received from the Person Responsible. The response states that the concerns of the inspection team have now been addressed.

3. The Committee noted the findings of the inspection team and endorsed the recommendation made. The Committee noted the response of the Person Responsible.

4. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

5. The Committee unanimously decided to grant a 5 year licence with no additional conditions.

6. The Committee requested that the licence only be issued on receipt of the licence fee.

Signed…… … Date……..
Jennifer Hunt (Chair)