Inspection Report

Date of Inspection: 5 October 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 7 hours
Inspectors: Sara Parlett (HFEA; Lead)
Parvez Qureshi (HFEA)
Kathryn Mangold (External inspector)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 24 September 2009 and 6 December 2011.

Date of Executive Licensing Panel: 20 December 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 (CoP), 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 continuation of the centre's licence.

Centre details

Centre Name	The Lister Fertility Clinic
Centre Number	0006
Licence Number	L0006/14/b
Centre Address	The Lister Hospital Chelsea Bridge Road London SW1W 8RH
Person Responsible	Mr Hossam Ibrahim Abdalla
Licence Holder	Ms Mary Power
Date Licence issued	01/03/2010
Licence expiry date	28/02/2014
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Lister Fertility Clinic has been licensed by the HFEA since 1993. The centre is housed within the Lister Hospital; an acute, independent hospital which is part of the HCA group of six hospitals in London.

The centre offers a comprehensive range of assisted conception therapies including insemination with partner/donor sperm, in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and embryo testing. The centre also runs an active egg share programme.

The centre is considered large and conducted approximately 3000 IVF/ICSI cycles from August 2010 to July 2011. The centre is open routinely for consultation and treatment from 8:00am to 6:00pm Monday to Friday and at weekends according to need.

The centre has satellite arrangements with two clinics and is in the process of setting up satellite agreements with other clinics. The Person Responsible (PR) is aware of the requirement to submit written agreements to the HFEA prior to starting a new satellite service (General Direction 0010).

The PR is an independent Consultant Gynaecologist and has been on the specialist register of the General Medical Council (GMC) for Obstetrics and Gynaecology since January 1997. The PR has been Medical Director of the centre since 1988, has successfully completed the HFEA PR Entry Programme (PREP) and has held the post of PR for many years.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 August 2010 – 31 July 2011*
IVF	1779
ICSI	1177
Frozen embryo transfer (FET)	408
Donor insemination (DI)	99
Intrauterine insemination (IUI) (01/01/2010 – 31/12/010)	297

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

Outcomes*
For IVF/ICSI/FET, HFEA held register data for the period May 2010 – April 2011 show the centre's success rates are in line with national averages, with the following exceptions: • The clinical pregnancy rates (CPRs) for both IVF and ICSI in the below 38 years age groups are above the national average at a statistically significant level. For the year 1 January to 31 December 2010 the centre reported 297 cycles of partner IUI with 29 pregnancies. This equates to a 10% 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 (ELP) is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four areas of major non-compliance and six other areas of non-compliance or areas of poor practice.

The ELP is also asked to note that the centre was proactive in addressing several of the areas of non-compliance highlighted on inspection soon after the inspection visit took place.

Since the inspection visit the centre has provided evidence that the following recommendations have been fully implemented:

Other areas of practice that require improvement

- To review and revise the centre's standard operating procedures (SOPs) for withdrawal of consent to the storage of embryos, blastocyst biopsy and the handling of returned material.
- To re-validate the centre's witnessing procedure post introduction of a new electronic witnessing adhesive label.
- To consider, based on the centre's patient demographic, the implications of not including all relevant patient populations in the centre's documented screening procedures for Human T-Lymphotropic virus (HTLV).

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

Major areas of non compliance

- To perform an audit of the consent to disclosure in patient records against the consent decisions which have been submitted to the HFEA.
- To take appropriate action regarding the continued storage of embryos being stored without valid consent.
- To ensure that:
    - All gamete movement in/out forms are retrospectively submitted for all relevant gamete transfers.
    - Centre processes are reviewed and revised to allow for the appropriate submission of all gamete movement in/out forms prospectively within the required timeframe.
- To ensure that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence are audited against compliance with approved protocols, regulatory requirements and quality indicators (QIs). It is also recommended that the PR considers widening the scope of the centre's witnessing audits.

Other areas of practice that require improvement

- To formalise the validation of all critical equipment in use.
- To ensure that future IUI returns are submitted within the timescales specified in General Direction 0005.
- To document the centre's systems for resolving data discrepancies.

Summary for licensing

The inspection team considers that, overall, there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation, it is noted that the PR has responded to all recommendations made in this inspection report.

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

Patients are provided with personalised costed treatment plans prior to treatment (CoP Guidance 4.3).

The nurse manager explained that price lists are given to patients as part of the patient information pack, prior to starting treatment. Costs are further discussed at the initial consultation and costed treatment plans are included in the cycle pack given to patients at this stage. The centre's price list details the costs of various treatment packages offered and additional costs, for example for drugs.

The treatment fees charged to clinics by the HFEA were reduced on 1 October 2011. At the time of the inspection these fee changes were reflected in the patient information price lists reviewed, but the centre's website had not yet been updated. This was discussed on inspection and a review of the website post inspection demonstrated that these price lists have since been modified.

Legal parenthood

Centre staff interviewed demonstrated an understanding of the legal parenthood provisions.

The centre has a SOP detailing all HFEA and centre specific consent forms that can be given to patients and the treatment scenarios for which each consent form is required. This includes consent to legal parenthood (Standard Licence Condition (SLC) T33 (b)).

The centre also has a SOP documenting the procedure to follow if consent to legal parenthood is withdrawn (SLC T33 (b)).

Patient information reviewed on inspection includes information on consent to parenthood, including the need of the partner to complete the HFEA PP consent form if the couple are married/in a civil partnership and the partner wishes to be the legal parent after his/her death.

The nurse manager explained that training sessions for all staff on obtaining consent have been conducted. A consent 'quiz' (see page 15 for further details) used as part of the staff competence assessment includes questions on when to obtain consent to parenthood and the procedure to follow when a person withdraws consent to being treated as the legal parent (SLC T15 (a)).

An audit of completion of consent to legal parenthood forms in 20 sets of relevant patient notes was performed in October 2010. The audit was reviewed on inspection and demonstrated that all relevant HFEA forms were completed appropriately in all cases (SLC

T36).

Four sets of records of patients who have undergone treatment using donor sperm were reviewed on inspection. Consent to legal parenthood was obtained appropriately in all cases.

What they could do better.

Nothing noted at the time of inspection.

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

What the centre does well.

Consent to disclosure

The centre seeks patient consent to identifying information from the HFEA register being disclosed to researchers. Registry information demonstrates that 44% of all patients and 42% of all partners who have been registered at the centre since October 2009 have opted in for disclosure.

The centre's patient information booklet gives information on the reasons for requiring consent to disclosure (CoP Guidance 5.26). The nurse manager explained that consent to disclosure is then discussed with the patient at the initial consultation appointment and consent is later obtained by nursing staff.

An audit of patient consents to identifying information from the HFEA register being disclosed to researchers, against that recorded on the HFEA register, was performed. With one exception, noted below, consenting decisions had been accurately reported to the HFEA.

Consent to storage

Consent to the storage of patient material is obtained by clinical staff. The laboratory manager explained that prior to storage, staff confirm that consent to storage is present and completed appropriately. This check step is recorded on a checklist kept in the patient notes. Five sets of patient notes audited on inspection were found to include appropriately completed storage consents.

Dewar audits are performed biennially (CoP Guidance 17.17 (a)). The most recent embryo and sperm audit reports were reviewed. The findings and corrective action taken were documented (SLC T36).

The centre's bring forward system for gametes and embryos in storage was described by the laboratory manager. Patients are contacted annually for the yearly billing of storage fees and twelve months prior to the end of the consented/statutory period a recorded delivery letter is sent. If no reply is received to this, a second letter is sent one month prior to the expiry date. The laboratory manager explained that if no response is received to this, telephone contact is attempted (CoP Guidance 17.18).

What they could do better.

Consent to disclosure

In one of the ten registration forms reviewed, a discrepancy was noted where a patient had not consented for non contact research, but this consent decision was incorrectly entered on the HFEA register. This inaccurate recording of patient consent to disclosure of

information for research purposes has been identified as an issue across the entire sector.

Consent to storage

The laboratory manager confirmed that all sperm samples currently in storage have appropriate consent. However, the embryos of six patients are currently in storage without valid consent (HF&E Act 1990 (as amended), Schedule 3, Paragraph 8(2)).

The laboratory manager confirmed that the embryos for three of these patients are scheduled for disposal and that disposal from storage is usually performed as a specific laboratory task every 8-12 weeks. The set of embryos with storage consent furthest out of date have been in storage without valid consent since 12 July 2011.

The laboratory manager explained that the remaining three sets of embryos have remained in storage due to on-going legal disputes with the gamete providers. The consents to the storage of these embryos expired in July and August 2011.

The laboratory manager explained that out of 3780 sets of embryos currently in storage at the centre, only three have been stored beyond the consented period, with the exception of those where a legal dispute is on-going. The laboratory manager stated that she feels this demonstrates the effectiveness of the bring forward system.

The laboratory manager described accurately the procedure that would be used for invoking the cooling off period for embryo storage and this procedure is documented. However, the SOP does not document that the 12 month period cannot extend beyond the end of the statutory storage period. Post inspection, the laboratory manager submitted a revised 'embryo consent and disputes' SOP which documents this (SLC T33 (b) and CoP Guidance 5.35).

Multiple births

For the 2010/11 time period the centre's multiple CPR for all IVF, ICSI and FET cycles for all age groups was 18%.

The centre's multiple CPR for 2010/11 represents performance likely to be better than the target multiple birth rate of 20%.

What the centre does well.

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

The centre has a detailed documented record of its multiple birth minimisation strategy (MBMS), including how the centre identifies suitable cases for elective single embryo transfer (eSET). This includes criteria in relation to patient selection and embryo assessment (General Direction 0003, 5 (a)).

The centre's MBMS also describes the centre's annual multiple CPR from 2002-2010 and the introduction of eSET in 2006, leading to a multiple CPR of 20% in 2006. This demonstrates the centre's proactive approach to reducing multiple births, prior to the regulatory requirements imposed by the HFEA.

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

- Staff were able to describe their progress towards reducing their multiple pregnancy

rates and subsequent multiple birth rates;

- Staff at the centre have audited their strategy and protocols as part of the quality management audit programme.
- Staff have maintained a log of women receiving multiple embryo transfers who meet the criteria for eSET, including the reasons for variation from the eSET policy and the pregnancy outcome. Three sets of patient records were reviewed on inspection and all documented the reasons for the variation from eSET. Evidence that discussions were held with patients regarding the risks associated with multiple pregnancy was seen in these patient notes (General Direction 0003, 3 (c) and 7).
- The centre maintains a summary log of cases in which three embryos have been transferred (General Direction 0003, 1 (b)). The log demonstrated that 82 patient have had three embryos transferred from April – August 2011. A detailed explanation of the reasons for three embryo transfers was seen documented in patient notes reviewed.

The centre's patient information was reviewed and found to be detailed in describing the risks of multiple pregnancy (CoP Guidance 7.7).

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

The laboratory manager confirmed that all critical processes have been validated. Validation records for several procedures, including semen preparation, ICSI, blastocyst vitrification and embryo biopsy were reviewed. Validation has been based on retrospective evaluation of the centre's own data and with reference to published studies, in compliance with SLC T72. Please refer to page 11 of the report for one exception regarding process re-validation.

The laboratory manager explained that inter-laboratory comparisons are conducted with two other licensed centres and an external advisor visits biennially to review laboratory procedures as part of the centre's process validation programme. Evidence of one such benchmarking activity conducted in January 2010 was seen on inspection (CoP Guidance 23.23).

The laboratory manager explained that the incubators are considered the most critical laboratory equipment and have been validated. Comprehensive validation documentation was seen to include records of commissioning, calibration to national standards, temperature mapping and failure mode simulations. Incubators are serviced six monthly and are monitored continuously (SLC T24).

What they could do better.

The laboratory manager explained that laboratory equipment other than the incubators are not considered as critical and have not been subject to a formal validation, but are serviced and monitored regularly. For example, the transport incubator is monitored weekly and the refrigerator is monitored continuously.

A full equipment qualification review, as recommended by the Association of Clinical

Embryologists (ACE) equipment validation guidelines has not been performed on equipment other than incubators (SLC T24).

Witnessing

What the centre does well.

The centre double checks 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 (SLC T71).

The centre has documented SOPs describing the witnessing procedure for all critical points specified in CoP Guidance 18.4. Witnessing steps observed during the inspection were performed in accordance with CoP Guidance.

Five sets of patient notes audited on inspection were found to include records of all required witnessing steps.

A radio frequency identification (RFID) electronic witnessing system is in use at the centre. The centre has identified the critical steps that must be witnessed manually; these include those required by CoP Guidance 18.33 and 18.35.

The electronic system was installed in 2009 and the laboratory manager confirmed that validation of the system and a risk assessment was carried out prior to its use. Validation included the use of the electronic system in parallel with the pre-existing manual system for three weeks prior to full implementation (SLC T24 and CoP Guidance 18.25).

The laboratory manager explained that if the electronic system fails, staff can revert to full manual witnessing. Laboratory worksheets for use in such a situation were seen on inspection (CoP Guidance 18.36).

Evidence of comprehensive training and competence assessment for staff performing witnessing steps, including training in the use of the electronic system, was seen on inspection (SLC T15 (a)).

The centre has established QIs for witnessing and audits of compliance with witnessing requirements are performed annually. The report of the last audit, performed in March 2011, was reviewed on inspection and documented a minor issue identified. The laboratory manager explained the corrective action that had been implemented as a result of this finding (SLC T35 and T36).

What they could do better.

The laboratory manager explained that since the introduction and validation of the electronic system at the centre, the adhesive used for the RFID labels had been modified by the company. No further validation to ensure that the new adhesive was not, for example, embryo toxic was undertaken by the centre. Post inspection the laboratory manager confirmed that the external company was in the process of sending the relevant validation documents for the new labels to the centre (SLC T73).

The electronic witnessing system documents the number of mismatches that have occurred. A mismatch is recorded by the system when non matching samples/patient identity cards are introduced into the same work area. When this occurs, the system alarms and the procedure cannot continue until a reason for the mismatch has been documented and the mistake rectified. The centre's witnessing audit scope does not

include a review of the number or type of mismatches that occur (SLC T36).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre has an egg share programme. It does not currently have an active sperm donor recruitment programme, but does accept known donors introduced by patients. The centre uses the services of an independent introduction agency and, to date, egg donors for ten patients at the centre have been recruited using this agency.

The centre's donor assessment and screening procedures for egg and sperm donors are supported by detailed SOPs, compliant with SLCs T52 and T53 (c), with one minor exception noted below. Six sets of sperm and egg donor records were audited during the course of the inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal history and medical examination performed by a clinician (SLC T52 (a)).
- Donors are being selected in accordance with the screening requirements of SLC T52 and relevant professional bodies[1]. Checklists are used to identify when additional screening may be required, for example for malaria (SLC T52 (h)).
- Donor sperm is quarantined for a minimum of 180 days, followed by repeat testing in accordance with SLC T53 (c).

Evidence of staff training and competence assessment for the selection and screening of donors was seen on inspection. The donor coordinator explained that competence is re-assessed six monthly (SLC T15 (a)).

The centre maintains detailed records on its database and can provide donors with information regarding the number, sex and year of birth of persons born as a result of donation (HFE Act 1990 (as amended), Schedule 31ZD (3)).

The donor coordinator explained that treatment services are always provided to egg share donors in the course of the donation cycle, unless there is a medical reason why they cannot be provided at the time. Embryos created are then frozen for use at a later date (General Direction 0001 (6)).

The senior nurse described the procedures in place for donor compensation, which were compliant with regulatory requirements. The centre maintains comprehensive donor expense records. All expense receipts are retained by the centre and loss of earnings compensation is given only upon receipt of pay slips or an appropriate letter from the donor's place of work.

The senior nurse confirmed that where donors have been recruited by the introduction agency used, the centre verifies that the donor has not received more than the prescribed amount of compensation. The introduction agency expense file was reviewed on inspection and was compliant with requirements (General Direction 0001).

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

What they could do better.

The centre's donor screening SOPs document the requirement for HTLV screening for certain patient populations, but do not specify all relevant high incidence areas (SLC T52 (g) and Health Protection Agency HTLV epidemiology analysis guidance).

The laboratory manager explained that donor sperm is regularly imported from America. However, no notification forms have been received since the last inspection for the import of donor sperm. The laboratory manager demonstrated the centre's computer system used for the submission of data to the HFEA and confirmed that the system did not currently allow for the submission of this form when donor sperm is imported.

Further examination of the HFEA Register post inspection demonstrated that forms are also not being submitted for the transfer of donor sperm within the United Kingdom, but are being submitted for the transfer of embryos. Post inspection, the laboratory manager stated that the centre is in the process of updating its database system to enable submission of the relevant forms (General Direction 0005).

Welfare of the Child (in relation to basic partner treatment services only)

What the centre does well.

Not applicable. This centre does not solely provide basic partner treatment services.

What they could do better.

Embryo testing (if applicable)

What the centre does well.

The centre is licensed for embryo testing and has performed fifteen cycles to date in 2011. The procedures for both cleavage and biopsy stage embryo biopsy are documented in SOPs, reviewed on inspection (see section below) (SLC T33 (b)).

The laboratory manager confirmed that no sex selection for social reasons is conducted at the centre (SLC T88 (b)) and that biopsied embryos are not transferred in the same cycle as non-biopsied embryos. This is also documented in the centre's SOPs (SLC T33 (b) and CoP Guidance 9.2).

The diagnostic analysis of blastomeres/trophectoderm for pre-implantation genetic diagnosis (PGD)/pre-implantation genetic screening (PGS) is undertaken by an external testing laboratory. The laboratory manager confirmed that the laboratory is in the process of obtaining CPA (UK) Ltd accreditation and aims to be accredited within ten months (SLC T21). The centre's third party agreement (TPA) with the testing laboratory was reviewed on inspection and is compliant with requirements (SLC T111 and T114).

QIs have been established for embryo biopsy and include blastocyst viability, damage rate and CPR (SLC T35). The laboratory manager confirmed that audits are performed annually, but that the low number of cases performed at the centre makes analysis of the results difficult. The report of a detailed audit performed in June 2011 was reviewed on inspection and includes a review of compliance with regulatory requirements and observations of staff performing the procedure. No corrective actions were identified (SLC

T36). The laboratory manager explained that the centre currently has four biopsy practitioners. Detailed competence assessments, including observation of biopsy skills, were reviewed on inspection (SLC T15 (a)).
What they could do better. The centre's SOP for blastocyst biopsy did not include the procedure for tubing and transport of the trophectoderm samples to the external laboratory for testing. Post inspection, the laboratory manager submitted a reviewed and revised SOP (SLC T33 (b)).

2. Changes / improvements since the previous inspection on 24 September 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Validation Validation of some critical equipment and key processes and procedures is not in place, Ref: S.6.4.2 and S.7.8.3 of the COP and standard licence condition A.11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of key equipment and processes considered to be most likely to impact on the quality of the service. CoP 8 SLC T24, T25, T28, T29, T30 and T31.	Refer to page 10 of report. **Further action is required.**
Competence Assessment Whist staff training logs and the framework for competency assessment is in some instances for laboratory staff are in place, nursing staff competency assessments have not being documented. A.10.11.	The centre should establish documented procedures for staff management that ensure that all staff have competence assessment. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. The PR must ensure and document that each individual has demonstrated confidence and competence in their designated tasks. CoP 8 SLC T12, T15 (a) and	Training programmes are in place for each department and a selection of staff training records were reviewed on inspection. Evidence of continued professional development, including attendance at conferences and courses was seen on inspection for all departments. Records of competence assessments for nurses and embryologists were reviewed on inspection and found to be comprehensive. A 'consent competency quiz' developed by the PR is used as part of the centre's framework for assessing staff knowledge and competence for obtaining consent. The quiz consists of a large number of questions including various treatment scenarios for which staff have to document the consent forms required, what to do if a patient wishes to withdraw consent at various points of the treatment pathway and information to be given prior to obtaining consent. The Executive commends the detailed and practical approach taken

Area for improvement	Action required	Action taken as evidenced during this inspection
	Guidance 2.1 (b).	to the assessment of competence to obtain consent (SLC T15 (a)). **No further action is required.**
Evidence of welfare of the child assessment The centre has a documented SOP in place for the assessment of welfare of the child (WoC). Documented evidence that this had taken place was absent in a number of patient records observed on inspection and in the centre's own patient records audit findings. CoP S.7.6.4.	The centre should ensure that a record of an appropriate WoC assessment having been conducted should be retained in the patients health record and be available for consideration prior to any treatment being conducted. CoP 8 SLC T56, T46 (e) and Guidance 8.18.	Centre staff confirmed that patient notes audits, including completion of WoC assessments, are conducted every two to three months and any discrepancies found are addressed (SLC T36). Two sets of patient notes were reviewed on inspection and included appropriately completed WoC assessments for both partners. **No further action is required.**
Document Control Not all documents viewed were appropriately controlled and reviewed within an appropriate time scale. CoP S.5.2.5.	The centre should ensure that all documents are generated, stored and released for use in accordance with the requirements of the Quality Management System. Such documents are to be regularly reviewed, revised, dated and re-approved for release. CoP 8 SLC T34 and	The centre's master document list was reviewed on inspection and demonstrated that documents are regularly reviewed and that access is controlled. The centre's document control SOP includes a description of the identifiers to be included on all documents, as required by CoP Guidance 31.4. Appropriate document control was evident on centre documentation provided during the inspection process. **No further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
	Guidance 31.4/5/6.	
Donor or potential donor screening Two patients who had consented to the posthumous use of their embryos in the treatment of others had not been screened as donors. S.7.4 G.5.4.	The centre should ensure compliance with the selection criteria for donors and the requirements for laboratory tests and storage and that documentary evidence is available in the potential donor's health record. SLC T52.	The new HFEA WT consent form, introduced in October 2009, does not give the patient the option of consenting to the posthumous use of eggs/embryos. Centre staff confirmed that if a patient were to consent to the posthumous use of embryos in the treatment of others, they would be required to register as donors and would be screened as donors. Refer to page 12 of report for discussion regarding donor screening. **No further action is required.**
Access to the medical records store was unprotected at the time of inspection when the room was unmanned. A.10.31.	The centre should ensure that access to patient health records is protected at all times. SLC T45.	Access to the laboratory and areas containing patient records were seen on inspection to be restricted to licensed staff. The door to the medical records store has a digital lock and was seen to be securely locked during the time of inspection. **No further action is required.**

Additional recommendations from the last ELP minutes (27 January 2010)

ELP Recommendation	Executive Review
The Panel noted that there is a concern over the numbers of staff at the centre, and noted that there were some posts vacant. The Panel recognises that the PR is actively recruiting for these posts and encourages the PR to monitor the levels of activity and available resources.	A highly detailed workforce analysis performed in June 2010 by the centre was reviewed on inspection. This included details of the increase in cycles performed at the centre, the dissatisfaction rates of patients regarding waiting times and an increase in written complaints. Due to these findings, a cap on the number of patients undergoing treatment was imposed and a recommendation for the creation of new posts was made. A number of people have since been recruited to posts at the centre, including two additional nurses and a new quality manager. The PR confirmed that workforce requirements are reviewed on an annual basis and reported that there is adequate staffing for the volume of work currently being conducted at the centre. It appeared at the time of inspection that personnel are available in sufficient numbers for present activity and workload (SLC T12). **No further action is 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
IUI data return The centre did not submit an annual return for IUI for 2010 to the Authority.	Centre staff confirmed that they had performed IUI cycles in 2010. Annual returns must be submitted to the Authority no later than 28 February in each calendar year (General Direction 0005 (paragraph 10). The annual return for 2010 was submitted by the centre on 17 October 2011.	**Further action is required.**
Outcome monitoring Cumulative sum (CUSUM) analysis of HFEA held register data has recently been introduced to allow for on-going assessment of CPRs at individual centres. CUSUM analysis of CPRs for ICSI in the below 38 years age group at the centre demonstrated a dip in ICSI success rates in April 2011. Data used for the statistical analysis of the centre's results is supplied by the centre itself and may be subject to	The CUSUM analysis was discussed in detail with both the PR and laboratory manager on inspection. The laboratory manager explained that due to the large number of cycles performed at the centre, QIs related to procurement and processing activities are audited monthly. It was confirmed that monitoring via QIs and audit had identified a reduction in embryo development and fertilisation rates in February 2011. This reduction had not dipped below the QI set thresholds but	While there was an apparent brief dip in ICSI success rates, the centre's overall performance in relation to ICSI in patients aged less than 38 years was above the sector average at a statistically significant level and no further action is required beyond that already taken by the centre. It is recommended that the PR audits the centre's data submission procedures, to ensure that all treatments, including early outcomes, are reported within the timeframes specified by General Direction 0005.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
change as errors are notified to the HFEA by the centre.	was lower in comparison to the data of the year prior. The detailed investigation performed, including a lengthy trial of a new type of media and the setting up of a London wide media user group, was described by the laboratory manager (SLC T35 and T36). However, this reduction in performance identified by the centre does not equate to the same time period indicated by HFEA statistical analysis. A small number of early outcome forms had not been submitted by the centre for March, April and May 2011, which can impact on the analysis. The PR stated that all treatments are reported to the HFEA on completion and that any missing treatments may be due to compatibility issues with the electronic data interchange (EDI). The PR confirmed that this would be reviewed to ensure that there is no back log.	**Further action is required.**
OHSS reporting No cases of OHSS have been reported to the HFEA by the centre (SLC T120).	The centre has a procedure in place for the management of OHSS and staff are aware of the reporting requirements. The PR reported that sometimes patients self admit to a local hospital, but do not report this to the centre. The PR	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	explained that the centre has recently changed its OHSS procedure to capture this.	
SAQ – Guidance Note 2: Staff Can all staff provide documented evidence of having demonstrated competence in their designated tasks. SLC T12 and T15(a).	Refer to page 15 of report.	**No further action is required.**
SAQ – Guidance Note 5: Consent Is the identity of the person giving consent verified when they give it. Is the identity of the person who gave consent cross-referenced to records when procedures are carried out. CoP Guidance 5.10 and 5.11 **SAQ – Guidance Note 31: Record keeping and document control** For each partner/donor, does the centre maintain a record containing: How, and by whom, the patient/donor has been reliably identified.	The centre's 'patient and donor identification' SOP was submitted pre inspection and includes the requirement to verify the identity of the patient/donor at all stages during consultation and treatment, including at registration and prior to obtaining consent. The SOP states that patients are required to bring passports to the initial consultation. Copies of the passport are taken, signed by the patient and kept in the patient notes for future identity verification. Confirmation that patient identity and signatures have been cross checked and match those on the consent forms is verified by nursing staff and recorded on a nursing checklist and filed in the patient notes.	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	Copies of passport identification and NHS numbers for both patient and partner were seen in the patient records audited on inspection (CoP Guidance 5.10 and 5.11).	
SAQ – Guidance Note 11: Donor selection Are donors of gametes and embryos screened in accordance with current professional guidance produced by the relevant professional bodies. CoP Guidance 11.15. Does the centre have procedures in place to identify when additional screening may be required? SCL T52(g).	Refer to page 12 of report.	**Further action is required.**
SAQ – Guidance Note 15: Procuring, processing and transporting gametes and embryos Does your centre have a procedure for handling returned gametes and embryos. Does your centre have a recall procedure that defines the responsibilities and actions required when a distribution is recalled.	The centre has a documented SOP for returning gametes/embryos to a centre if, for example, they are received with incomplete documentation. An incident occurred at the centre in 2009 that required the handling of returned gametes. This recall was investigated as an adverse incident. However the procedure for handling of returned material has not been documented (SLC	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Does your centre have a procedure for the investigation of any recall as an adverse incident CoP interpretation of mandatory requirements 15B.	T33 (b)). Post inspection, the laboratory manager submitted a revised 'transport' SOP. This documents the procedure for the handling of returned material.	
SAQ – Guidance Note 23: The quality management system Has your centre established quality indicators for all licensed activities and for other activities carried out in the course of providing treatment services that do not require a licence. SLC T35. In the last two years, has your centre audited how far all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence, comply with the approved protocols, the regulatory requirements and quality indicators. SLC T36.	The centre has established QIs, including for counselling, provision of information to patients, consent, donor screening and traceability, but not for the submission of data to the HFEA (SLC T35). The centre's audit schedule was reviewed on inspection and demonstrated that the majority of audits have been completed, including those for procurement and processing activities and the remaining are due for completion by the end of the year. Audits that are currently in progress are for counselling, provision of information and consent. Audits of submission of data to the HFEA have not yet been performed. Evidence of the documentation of audit findings and the implementation of identified corrective action was seen in a selection of audits reviewed on inspection (SLC T36).	**Further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
SAQ – Guidance Note 24: Third party agreements Where a third party procures gametes and/or embryos on behalf of your centre, does the third party provide a report that complies with SLC T117. Does the content of all TPAs comply with standard licence condition SLC T114.	The centre uses the services of an agency to introduce recipients to potential donors. The centre's TPA with the agency was reviewed and the contents appeared compliant with requirements (SLC T117). Three TPAs were reviewed on inspection and were compliant with the requirements of SLC T114.	**No further action is required.**
SAQ – Guidance Note 25: Premises and facilities Are laboratories that undertake the diagnosis and investigation of your centre's patients, patients' partners or donors, or their gametes, embryos or any material removed from them, accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. SLC T21.	Centre staff confirmed that laboratories undertaking diagnosis and investigation of patients are accredited by CPA (UK) Ltd, with one exception noted below. Reports of test results observed in patient notes reviewed on inspection were all from CPA accredited laboratories (SLC T21). See page 13 of the report for further details regarding the accreditation status of the external laboratory performing diagnostic analysis of blastomeres/trophectoderm.	**No further action is required.**
SAQ – Guidance Note 27: Adverse incidents Are third parties aware of the requirement to report adverse incidents to the primary centre.	Centre staff confirmed that third parties are aware of the requirement to report adverse incidents, but this is not documented in the TPAs. Staff confirmed that they will update the TPAs to reflect this requirement.	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	The centre submitted two reviewed satellite agreements post inspection. These include the requirement for the satellite centre to report adverse incidents to the primary centre.	
SAQ – Guidance Note 30: Confidentiality and privacy Does the SOP for the control of access to health data and records: • Document the systems in place for establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records; and the transfer of information. • Document the systems in place for establishing and maintaining procedures to resolve all data discrepancies. • Document the systems in place for receiving, checking and arranging authorised access to confidential data and records. SLC T44 (a), (b) and (e).	The centre's control of access to health and data records was reviewed on inspection and documents the systems in place for maintaining data security. Procedures are also in place for access to confidential data and records (SLC T44 (a) and (e). Centre staff confirmed that the systems in place for resolving data discrepancies have not been documented and this is due to be done towards the end of the year (SLC T44 (b)).	**Further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
SAQ – Guidance Note 30: Confidentiality and privacy Is access to areas where confidential identifying information can be seen or obtained (records stores, laboratories, cryostores etc.) restricted to people authorised by the PR. HF&E Act 1990 (as amended), section 33A (1).	Refer to page 17 of the report.	**No further action is required.**
SAQ – Guidance Note 31: Record keeping and document control Does your centre have a document control procedure that records the history of document reviews and ensures that only current versions of documents are in use. SLC T34.	Refer to page 16 of the report.	**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 CoP, 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, 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 noted at the time of 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
Consent to disclosure to researchers In one of the ten registration forms reviewed on inspection, a discrepancy was noted where a patient had not consented for non contact research, but this consent decision was not correctly entered on the HFEA register. General Direction 0005.	The PR should ensure that the discrepancy noted on inspection is corrected on the HFEA register. Immediately The PR should conduct an audit of a representative number of consent to disclosure forms (completed since October 2009) in the patient records against the consent decisions that have been submitted to the HFEA. The findings of the audit and any relevant corrective actions should be documented and a copy provided to the Executive by 6 January 2012.	The consent to research has been amended on the HFEA Register for the patient concerned. An audit is currently underway to review 250 sets of notes. The audit findings and any relevant corrective actions will be submitted to the HFEA by 23.12.2011.	The Executive is satisfied with the PR's response and will continue to monitor progress.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	If the audit findings indicate a systemic problem, a full audit of all consent to disclosure forms completed since October 2009 may be required. The PR should ensure that in future, all data submitted regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record.		
Embryo storage At the time of inspection the embryos of six patients were being stored without valid consent. HFE Act 1990 (as amended), Schedule 3, paragraph 8 (2).	The PR must take appropriate action regarding the continued storage of the three sets of embryos scheduled for disposal and inform the Executive of the action taken. By the time the PR responds to this report. The PR should provide an update regarding the three sets of embryos stored without valid consent, where legal disputes are occurring. By the time the PR responds	Three sets of embryos due for disposal have been disposed of. The disposal SOP has been amended to state that embryos will be discarded within 2 week of receipt of the consent to disposal. A report will be run every 2 weeks to show any embryos outside of the consented period. Of the 3 sets of embryos with legal disputes, 2 have been	The centre has submitted its disposal of stored material SOP, documenting the revised procedure for removing material without valid consent from storage. The Executive is satisfied with the PR's response. The PR is requested to give regular updates to the Executive regarding the one set of embryos currently in storage without consent.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	to this report. The PR should review the centre's practice of removing material from storage every 8-12 weeks, rather than on the date of consent expiry. This should include following guidance in the HFEA Chair's letter 03(03) regarding how often to carry out this procedure. For completion by 6 January 2012.	resolved and disposed. The remaining set of embryos are still in storage, Mr Abdalla has written to Mr Alan Dorran (HFEA) letter dated 17th Oct 2011 , to ask if the HFEA should seek legal advice regarding this patients request to extend storage.	
Form submission Embryo/gamete movement in forms have not been submitted to the HFEA for the import of donor sperm. General Direction 0005.	Post inspection, the laboratory manager stated that the centre is in the process of fixing its database system to enable submission of the relevant forms. The PR should ensure that this system update allows for appropriate submission of all embryo/gamete movement forms prospectively within the required five working days. The PR should ensure that gamete movement in/out forms are retrospectively submitted	This is a computer issue which we are resolving. This will be completed before 5th Jan 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Early outcome form submission	for all relevant transfers. This includes transfers within the United Kingdom. For completion by 5 January 2012.		
QI and Audit QIs for the submission of data to the HFEA have not been established. Audits have not been performed/completed for all activities in the last two years including audits of submission of data to the HFEA. SLC 35 and T36	The PR should ensure that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, are audited against compliance with approved protocols, regulatory requirements and QIs. It is recommended that QIs/audits of submission of data to the HFEA include ensuring that all required forms are reported within the timeframes specified by General Direction 0005. For completion by 6 April 2012	We are currently establishing QI's for the submission of data and this will be audited by 6th April 2012. An audit of Electronic witnessing mismatches has now been performed and a copy has been submitted to our HFEA Inspector. No issues were identified. The Laboratory Manager will run off this report monthly to review the mismatch report and this will be included in the scope of our witnessing audits in future.	The centre has submitted the report of a witnessing mismatch audit performed on 14 November 2011. The report includes corrective action identified and implemented. The Executive is satisfied with the PR's response and will continue to monitor progress.
The centre's witnessing audit scope does not include a review of the number or type of	It is recommended that the PR considers widening the scope of the centres witnessing audit to include a review of the	An audit of CD consents and Counselling are in progress.	

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
mismatches that occur using the electronic witnessing system. SLC T36.	number/type mismatches that occur. To review at the next inspection.	Audits for Provision of information had been completed at the time of inspection. We did state that we were looking to do a more detailed analysis in view of the responses from our patient feedback questionnaire.	

Other areas of practice that require improvement

Other areas of practice that require 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
SOP review and revision The SOP describing the procedure used for invoking the cooling off period for embryo storage does not document that the 12 month period cannot extend beyond the end of the statutory storage period. SLC T33 (b) and CoP Guidance 5.35.	Post inspection, the laboratory manager submitted appropriately reviewed and revised SOPs. **No further action is required.**	N/A	N/A

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre's SOP for blastocyst biopsy did not include the procedure for tubing and transport of the trophectoderm samples to the external laboratory for testing. SLC T33 (b). The centre's procedure for the handling of returned material has not been documented, including: • Definitions of the responsibilities and actions required when a distribution is recalled. • The requirement to handle a recall as an adverse incident. SLC T33 (b).			
Process re-validation The adhesive used for the RFID labels had been modified by the company. No validation to ensure that the new adhesive was not, for example, embryo toxic was undertaken.	Post inspection the laboratory manager confirmed that the external company was in the process of sending the relevant validation documents for the new labels to the centre. The PR is asked to inform the	The re-validation of RFID adhesive tags has been completed and a copy is attached.	The centre has submitted evidence of validation of the new adhesive labels. No further action is required.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
SLC T73	Executive when the re-validation of the process has been completed. For completion by 6 January 2012.		
Equipment validation The laboratory manager explained that laboratory equipment other than the incubators are not considered as critical and have not been subject to a formal validation, but are serviced and monitored regularly. A full equipment qualification review, as recommended by the Association of Clinical Embryologists (ACE) equipment validation guidelines has not been performed on equipment other than incubators. SLC T24.	It is recommended that the PR formalises the validation of all critical equipment in use, to the same extent as the incubators. For completion by 5 October 2012.	Validation of the Fridge and the transport incubator has been completed. A copy is attached. Validation of the flow hoods will follow in due course.	The centre has submitted validation documentation for the refrigerator and transport incubator. The Executive is satisfied with the PR's response and will continue to monitor progress.
Donor Screening The centre's donor screening SOPs document the requirement for HTLV screening for certain patient	It is recommended that the PR consider, based on the centre's patient demographic, the implications of not including all relevant patient	The Donor screening SOPs have been updated to include the relevant patient populations for HTLV. A copy is attached.	The centre has submitted revised donor screening SOPs. These specify all relevant high incidence areas relevant to HTLV screening.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
populations, but does specify all relevant high incidence areas. SLC T52 (g) and Health Protection Agency HTLV epidemiology analysis.	populations in the centre's documented screening procedures. For completion by 6 April 2012.		No further action is required.
IUI data submission The centre did not submit an annual return for IUI for 2010 to the Authority. General Direction 0005	The annual return for 2010 was submitted post inspection. The PR is reminded of the requirement for submission of future IUI returns within the timescale specified by General Direction 0005 (paragraph 10).	Please can we request that a copy any emails and letters to the PR are copied to the Quality Manager.	The request has been duly noted by the Executive. However, reminders for submission of IUI returns are not sent to centres. General Direction 0005 requires submission of the IUI annual return no later than 28 February, each calendar year. The Executive will monitor compliance by confirming submission of the centre's 2012 form.
Control of access to health data and records SOP Centre staff confirmed that the systems in place for resolving data discrepancies have not been documented and this is due to be done towards the end of the year. SLC T44 (b).	The PR should ensure that systems in place for resolving data discrepancies are documented. For completion by 6 April 2012.	In Practice, Data discrepancies are dealt with by the Department Managers or Quality Manager as they happen. We are currently in the process of documenting this practise in detail.	The Executive is satisfied with the PR's response and will continue to monitor progress.

Additional information from the Person Responsible
Please can we request that a copy any emails and letters to the PR are copied to the Quality Manager. julieivoska@LFClinic.com The above request has been duly noted by the Executive (S. Parlett; 29 November 2011).

HFEA Executive Licence Panel Meeting

20 December 2011

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

Minutes – Item 6

Centre 0006 – (The Lister Fertility Clinic) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	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 1993, and is housed within the Lister Hospital; an acute, independent hospital which is part of the HCA group of six hospitals in London.

2. The Panel noted the centre offers a comprehensive range of assisted reproduction therapies including insemination with partner/donor sperm, in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and embryo testing. The Panel noted the centre also runs an active egg sharing programme.

3. The Panel noted that the centre has satellite arrangements with two clinics and is in the process of setting up satellite agreements with other clinics.

4. The Panel noted that the Person Responsible (PR) is an independent consultant gynaecologist and has been has been on the specialist register of the General Medical Council (GMC) for obstetrics and gynaecology since January 1997. The PR has been medical director of the centre since 1998, and is also an Authority member of the HFEA.

5. The Panel noted that the centre conducted approximately 3000 IVF/ICSI cycles from August 2010 to July 2011. The Panel also noted that HFEA held registered data for the period May 2010 – April 2011 showed that the centre's success rates for IVF, ICSI and frozen embryo transfers (FET) are in line with national averages, but that the clinical pregnancy rates for IVF and ICSI in the below 38 age group are above the national average. And for 2010 the centre reported a 10% pregnancy rate for partner intra uterine insemination (IUI).

6. The Panel noted the centre's multiple pregnancy rate (CPR) for the period of 2010/11 for all IVF, ICSI and FET cycles for all age groups was 18%, which will be below the target multiple birth rate of 20%. The Panel also noted that on-going monitoring of the centre's multiple CPR suggests that the centre is unlikely to exceed the 2011/12 multiple birth rate target of 15%.

7. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement; four areas of major non-compliance and six other areas of non-compliance or areas of poor practice.

8. The Panel noted that since the inspection the centre has been proactive in addressing several of the areas of non-compliance identified. The PR has implemented three of the other areas identified on the inspection and given a commitment to fully implement the four major areas of non-compliance and three other areas of non-compliance that remain outstanding.

9. The Panel noted the Inspectorate recommends the continuation of the centre's licence with no additional conditions.

Decision

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

Signed: Peter Thompson Date: 10/1/12.
Peter Thompson (Chair)