Interim Inspection Report

Date of Inspection: 26 July 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 9 hours
Inspectors: Wil Lenton (HFEA Executive, Lead)
Sara Parlett (HFEA Executive)
Ellie Suthers (HFEA Executive)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 28 April 2009 and 4 November 2011.

Date of Executive Licensing Panel: 18 November 2011

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

Centre details

Centre Name	London Fertility Centre
Centre Number	0088
Licence Number	L0088/17/d
Centre Address	53 Portland Place London United Kingdom W1B 1QJ
Person Responsible	Mr Magdy Asaad
Licence Holder	Dr Brendan Ball
Date Licence issued	31/08/2009
Licence expiry date	31/08/2013
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 centre has seen much organisational change over the past eighteen months, most notably the change of ownership which occurred on 29 March 2010. The centre is now part of the Spire Healthcare group. There have also been significant staff changes over the same time period, including the laboratory manager, research Person Responsible (PR), Licence Holder (LH) and centre manager.

There have been two changes of LH involving all three London Fertility Centre (LFC) licenses (L0088/L0308 and R0169). These changes were approved by ELP on 28 July 2010 and 3 December 2010.

The centre is open seven days a week but oocyte retrievals are not routinely scheduled for weekends.

The centre currently has links to twenty satellite centres.

The PR, Mr Magdy Asaad, is appropriately qualified (General Medical Council number 3160974), and has successfully completed the PR Entry Programme (PREP number T/1051/7).

Variation to Licence.
During the post-inspection period the Executive was informed that the centre wishes to vary its licence in order to change its current Licence Holder (LH), associated with;

i. the treatment and storage licence (L0088/17/e; which expires on 31 August 2013)
ii. the research licence (R0169/4/e; which expires on 31 December 2011)

The Executive has received an application form and all other required documentation as specified by General Direction 0008. An Executive Summary together with all required documentation is included with the inspection papers for consideration by the ELP.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 Jun 2010 - 31 May 2011*
In Vitro Fertilisation (IVF)	340
Intra Cytoplasmic Sperm Injection (ICSI)	205
Frozen Embryo Transfer (FET)	116
Donor Insemination (DI)	35
Intra Uterine Insemination (IUI)	63
Egg donation (non egg share)	17

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period March 2010 - February 2011 show the centre's success rates are in line with national averages.

For the year 2010 the centre reported 63 cycles of partner IUI with 4 clinical pregnancies. This equates to a clinical pregnancy rate of 6%.

*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

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;

- eight major areas of non-compliance and
- six other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and/or provided evidence that the following recommendations have been fully implemented

Major areas of concern

- The centre has reviewed and updated its Multiple Births Minimisation Strategy (MBMS)
- The centre has reviewed and amended its payment policy to sperm donors in line with current Directions
- The centre has reviewed and amended its standard operating procedure (SOP) for witnessing
- The centre has liaised with the HFEA Register team to ensure that all information submitted is accurate

Other areas of concern

- The centre has developed procedures to be undertaken in the event of critical equipment malfunction
- The centre has reviewed and amended the success rates published on its website
- Laboratory cleaning records are now being accurately maintained
- The centre has split oncology patient cryo-stored semen samples between different cryo-dewars

Although the PR has given a commitment to implementing the following recommendations, there are still further actions required with respect to;

Major areas of concern

- The diagnostic laboratory used to assess embryo biopsies should be clinical pathology accredited (CPA)
- The embryo biopsy processes & equipment should be validated
- The centre has to assess its present administrative and clinical staffing resources against its current level of treatment activity
- The Quality Management System (QMS) should be better maintained

Other areas of concern

- The centre should review/amendment its SOP for gamete/embryo transport
- The centre should review/amendment its third party agreements (TPA's)

Recommendation to the Executive Licensing Panel

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 of the recommendations made in this inspection report and that further improvement is required in only a few areas of practice. In order to enable the Executive to monitor the progress made in resolving these outstanding issues, the inspection team recommend that the PR submits a quarterly update to the centre's inspector, giving details of any specific progress made and providing any related evidence of compliance.

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:** The PR and general manager explained that patients are provided with information about the cost of treatment from various sources. Initially this information is available to prospective patients via the centre's website. At an initial consultation the patients are given a comprehensive pricelist, together with a letter specifying the cost of each element of their treatment, which includes drugs and investigations, a copy of which is included in the patient's notes. The PR explained that the patient is informed that the costs may vary according to their treatment pathway, or their response to drugs. Any changes to the patient's treatment are discussed with them as the cycle progresses (G4.3). **Legal Parenthood:** The PR explained that there is a SOP in place for staff to follow when taking patient consent (standard licence condition (SLC) T33b), and that patients and partners are informed about parenthood laws at the first consultation, prior to any consent to treatment being taken (SLC T63). The PR explained the process of informing the patient about the requirements for any second parent, including which consent forms would need to be signed and also the process to be followed should a patient or patient partner wish to withdraw their consent (SLC T64).
What they could do better. **Legal Parenthood** Although staff were able to describe the process which they would follow, should a patient or patient partner wish to withdraw their consent to legal parenthood at any time, there was no documented procedure in place for this process (SLC T33b). The senior nurse indicated that the consent SOP was presently being reviewed and amended, to include actions to be taken if a second parent wanted to withdraw their consent.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure of identifying information to researchers** The centre seeks patient consent to identifying information from the HFEA Register being disclosed to researchers. The HFEA Register information demonstrates that 21% of all patients and 19% of partners, who have been registered at the centre since October 2009, have opted in for disclosure. A sample of consents to the disclosure of personal information held on the HFEA Register was reviewed on inspection. The consents, recorded in six sets of patient records, were found to be consistent with the consenting decisions reported to the HFEA, except for the two cases detailed below. **Consent to storage** The centre has a documented SOP in place for the storage of patient gametes and embryos (SLC T33b). The PR stated that consents to storage are checked prior to freezing of any licensed material and that the centre has a 'bring forward' system in place in order to continually monitor patient storage consent expiry dates. (Code of Practice (CoP) Guidance 17.17). The PR demonstrated an awareness of the cooling off period for patients embryos, in cases where individual gamete providers may want to withdraw their consent, but explained that only one such case had arisen during the last seven years, and that this case was prior to the cooling off period being implemented. The centre presently has no embryos in storage which are involved in a cooling off issue.
What they could do better. During an audit of patient records the consent to disclosure of identifying information to researchers was found to have been recorded and submitted to the Register incorrectly on two occasions. In both of the above instances the centre had recorded that patients had not consented to contact by researchers, when in fact they were happy for them to do so (SLC T9e).

Multiple births
For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%[1]. The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to meet the target at a statistically significant level and is unlikely to be due to random variation.
What the centre does well. On-going monitoring of the centres multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123) The PR has provided some evidence to demonstrate general compliance with HFEA Directions 0003 in that: • they were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates. The centre had documented evidence of a meeting which took place on 16 June 2011 to discuss development of the centre's MBMS, even though, due to a technical problem with the centres database, not all relevant data was available.
What they could do better. During discussions with the PR it was stated that the centre had experienced problems retrieving data from the centre's database and due to this; • staff at the centre were unable to retrieve all relevant data with which to audit their strategy and protocols as part of the QMS audit programme; • the centre was unable to demonstrate the maintenance of a log of women receiving multiple embryos who meet the criteria for single embryo transfer; and outcomes which are recorded in patients records (General Direction 0003).

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

Validation of critical equipment and processes
What the centre does well. Documentation was in place concerning the validation of most critical processes and equipment (SLC T24/T72). Critical procurement and processing procedures are documented in SOPs as part of the centre's QMS (SLC T33b). Critical equipment is serviced and maintained at regular periods and is monitored on a daily basis. The centre has incorporated a, 'Facilities Monitoring System' (FMS), which automatically records critical parameters such as, individual incubator temperature and carbon dioxide levels, cryo-vessel temperatures and air particle counts (SLC T23/T24). Laboratory key performance indicators (KPIs) are recorded daily and evaluated periodically by the laboratory staff, as part of the on-going monitoring process and equipment validation process (SLC T72 and T24)
What they could do better. A dry-shipper used within the laboratory has not been validated (SLC T24). Although laboratory staff could describe the process for revalidation of equipment following repair, currently there is no written SOP in place for this process (SLC T33b).

Witnessing
What the centre does well. To ensure that patients receive treatment using the correct gametes or embryos, the centre double checks the identification of gametes and embryos against the patient or donor to whom they relate, at all critical points of the clinical and laboratory process. The centre has a SOP in place for the witnessing process, which was reviewed by the centre in June 2011 (SLC T33b). Observation of the witnessing process was undertaken on the day of inspection, together with a review of five sets of patient notes. Generally the witnessing process was seen to be compliant with SLC T71, except for the issues noted below. The centre is intending to install an electronic witnessing system in the near future.
What they could do better. Presently, there are no witnessing steps covering; • the disposal of gametes/embryos. • confirmation that the male partner has checked that the relevant identifying information is correct at sperm production • that the identifying details on the cryo-straw are checked against the identifying details on the corresponding thaw dish, during embryo thawing • when embryos are transferred from the culture dish to the cryo-straw, during embryo freezing (SLC T71).

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The centre has a SOP in place for the selection and recruitment of sperm donors (SLC T33b). Staff stated that sperm donors are selected on the basis of their age and via the completion of a socio-medical questionnaire undertaken by a clinician. During the review of a set of sperm donor records, it was established that all required, applicable screening tests are currently being undertaken by the centre in accordance with professional guidelines. These are recorded on a donor recruitment checklist, which gives details of all screening tests completed (SLC T52). All donor screening tests are undertaken in a Spire Healthcare CPA-accredited pathology laboratory (SLC T53a).
What they could do better. The centre presently pays sperm donors a flat rate payment per donation, up to a maximum of £250. All payments to donors are logged in the donor file, but no individual donor travel expenses records, including receipts are presently kept. In this respect the centre is not compliant with General Direction D0001.

Embryo testing (if applicable)
What the centre does well. The laboratory Director stated that prior to major organisational and personnel changes in 2010, there had been two experienced in-house biopsy practitioners, but that both had now left the centre. The centre has undertaken ten biopsy cases in the current year, for which a locum biopsy practitioner was used. In the majority of cases, the locum biopsy practitioner used by the centre, was one of the practitioners that had previously left, and was therefore suitably trained, experienced and familiar with the centre equipment and processes. A documented SOP is in place for embryo biopsy (SLC T33b). The laboratory Director confirmed that biopsied embryos are not transferred alongside non-biopsied embryos, that treatment is only provided for conditions approved by the Authority and that no cases of sex selection for social reasons have been undertaken at the centre (SLC T88).
What they could do better. The embryo biopsy process and equipment have not been validated (SLC T24 T72). There was no documentary evidence of the periodic assessment of the competence of any biopsy practitioner (SLC T12). The laboratory which undertakes diagnostic tests, on biopsied cells supplied from the centre, is currently not CPA accredited (SLC T21).

2. Changes / improvements since the previous inspection on 28 April 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
There has been no documented validation of laboratory procedures to ensure the safety and quality of patient gametes and embryos T72	Validation of laboratory procedures should be undertaken to ensure the safety and quality of gametes and embryos	Documentation was in place concerning the validation of most critical processes (SLC T72). The process and equipment involved in embryo biopsy has not been validated, together with a dry-shipper used within the laboratory (SLC T24/72). **Further action required.**
It was noticed that the centre displayed 'success rate' & 'clinical pregnancy rate' data for the years 2007 and 2008 instead of the more accurate 'live birth rate' data on their website.	The centre should ensure that accurate information relating to live birth rates are made available via the centre's website.	When checked, prior to inspection on 25 July 2011, the centre's website was purporting to displaying HFEA success rate data for 2009. This information was not verified HFEA data as all such data is based on live birth outcomes. The centre should ensure that all patient information displayed on their website is accurate (G4.2e) As this was also an issue at the previous inspection, the PR should take immediate action to ensure that any information displayed on the centre's website is in line with Chairs letter CH(11)02. **Further action required.**

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
1. Guidance Note 2: Staff: Is the centre operating with a full staff complement? Assessment of staff competence	The centre has seen much organisational change since being incorporated into the Spire Healthcare group in March 2010. There have been significant senior staff changes, including the centre manager, quality manager, laboratory manager, nurse manager, LH and research PR. Due to these changing circumstances, over the last eighteen months, the centre has primarily focussed on the continuity of patient services. It was observed that the laboratory had recently lost a team member, due to a visa requirement, but that this had been compensated for by the recruitment of another experienced embryologist. A new nurse manager has also recently been recruited and was present during the inspection. The centre has not recently assessed the staffing resources required in order to safely deliver the treatment services it presently provides. There was no documented SOP in place for new staff induction training and competence assessment There was no evidence of the documentation of the assessment of staff competence in the following areas; • Embryo biopsy	Although the centre is continuing to deliver patient services with its present staff complement, it is recognised that more staff are required throughout the centre. The centre should assess its present service activity against staffing resources available, in order to highlight any present staffing requirements. Going forward the centre should periodically assess service workload against staffing resources as part of the QMS, in order to ensure that there is adequate staff available to safely deliver patient services (G23.12). A documented SOP should be developed for new staff induction and competence assessment (SLC T33b) Periodic assessment of staff competence should be undertaken and documented (SLC T12).

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	• Donor recruitment, assessment & screening • Witnessing • ICSI	**Action required**
2. Guidance Note 23: The Quality Management System (QMS).	During the course of the inspection, the PR and general manager acknowledged that due to the organisational and personnel changes over the last eighteen months, referred to above, the centre has not prioritised the maintenance of its QMS. Due to this fact the following areas of practice have not been audited within the last two years: • Consent • Welfare of the Child • Embryo biopsy • Donor selection and screening • Donor payments • Traceability • Storage QI have not been developed in the following areas: • Information given to patients • Consent • Welfare of the Child • Embryo biopsy	This issue is to be addressed within the forthcoming months by the centre. They intend to utilise an established Spire Healthcare 'Clinical Governance and Quality Assurance Strategy' and incorporate areas such as staff induction, training and competence assessment, audit of practice, quality indicator development, patient complaints and feedback. This would ensure that a rolling audit scheme was implemented to target any missing areas of service delivery, together with the establishment of any outstanding QIs. The Spire Healthcare quality management framework was demonstrated by the general manager via the Spire intranet, which is available to all staff at the centre. Presently Spire Healthcare has a quality management framework in place, across its thirty-seven hospital sites, which addresses quality issues in line with the Care Quality Commission requirements. This framework is presently being reviewed and amended by the general manager to incorporate HFEA requirements. During the inspection, the general manager presented a formulated annual clinical audit programme for the centre going forward.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	• Donor selection and screening • Donor payments • Procuring and processing • Witnessing • Traceability • Data submission to the HFEA SOPs need to be developed in the following areas; • new staff induction training and assessment of competence • withdrawal of consent to legal parenthood • revalidation of equipment following repair • donor recruitment and screening • completion of eSET log on centre's database • recall of transported material It was also observed that there was a lack of both document control and document review on some of the documentation assessed by the inspection team.	This also included proposed QI development. The centre should perform audits of practice, against compliance with the approved protocols, regulatory requirements and QIs for all activities presently undertaken at the centre (SLC T36) and develop relevant QIs for each of these activities (SLC T35). Documented SOPs should be developed in the areas identified (SLC T33b). A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). **Action required**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
3. Guidance Note 15 Procuring, processing and transporting gametes and embryos	The transport of gametes/embryos SOP does not document that; • transport conditions such as temperature and time limit are specified • the actions required in the event of a shipment recall	Review/amendment of transport of gametes/embryos SOP required (SLC T107 G15C) **Action required**
4. Guidance Note 17 Storage of gametes and embryos	Cryopreserved semen samples for oncology patients are not being divided into different cryo-storage vessels.	Cryopreserved semen samples for oncology patients should be divided into different cryo-storage vessels. (G17.7) **Action required**
5. Guidance Note 24 Third party agreements	During an audit of centre TPAs, it was found that the ones concerning the; • courier service • embryo testing service did not comply with licence condition requirements.	All TPAs should be reviewed/amended in order to ensure that they meet the requirements of the relevant licence conditions and guidance set out in CoP8 (SLC T116). **Action required**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
6. Guidance Note 26 Equipment and materials	During discussions with staff it was identified that; • some equipment SOPs do not include instruction on actions to be taken following equipment malfunction • Some corrective actions are required for laboratory heated stages • Staff are not ensuring that equipment and premises cleaning records are being updated	Equipment SOPs need to be reviewed/amended to include actions to be taken in case of malfunction (SLC T27). Corrective actions should be undertaken promptly for critical equipment such as laboratory heated stages (SLC T24). Cleaning records for equipment and premises should be accurately maintained (SLC T26). **Action required**

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions 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
Nothing noted			

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
Diagnostic testing of embryo biopsies is currently being performed in a non-CPA accredited laboratory. (SLC T21)	The laboratory performing diagnostic embryo biopsy testing for PGS/PGD should be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. The PR should ensure that all diagnostic embryo biopsy testing for PGS/PGD is conducted in a laboratory accredited by CPA(UK) Ltd or another body accrediting to an equivalent standard The PR should report to the inspector when any significant progress has been made, as part of the on-going monitoring process.	The PR recognises the need for the external laboratory to be accredited by the CPA (UK) Ltd or another body accrediting to an equivalent standard and has already been in touch with them to pursue this further. The company involved is presently in the process of applying for CPA accreditation. This process is realistically expected to take some more months to achieve. The PR at LFC will be informed once accreditation has been approved.	In order for the Executive to continue to monitor this issue, the PR should provide a quarterly update concerning any progress made by the diagnostic company in achieving CPA accreditation, or equivalent. The PR should forward the first quarterly update by 31 December 2011, and continue until the issue has been resolved. **Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Some critical processes & equipment have not been validated. (SLC T24 T72)	As this was an issue at the previous inspection the PR should ensure, without further delay, that appropriate validation of all critical processes and equipment is in place by 26 October 2011.	The PR has supplied documentation showing that the dry-shipper used within the laboratory has been validated.	The PR has supplied documentation showing that the dry-shipper used within the laboratory has been validated. There has been no such validation documentation concerning the embryo biopsy process or equipment. The PR should forward the relevant embryo biopsy process and equipment validation documentation by 31 December 2011. **Further action required.**
The QMS has not been well maintained since March 2010, due to organisational and personnel changes. There are now outstanding issues relating to; • SOP development • Audits of practice • QI development • Document control which need to be addressed as a matter of some urgency.	The PR should ensure that; • Audits of practice are undertaken • QIs are developed for all areas of practice • SOPs are in place for all centre activities • Document control and document review procedures are in place. The PR should provide an action-plan and time-line for the implementation of all QMS improvements to the inspector by 26 October 2011. The PR should also ensure that the	An action-plan and time-line for the implementation of QMS improvements has been provided by the PR.	In order for the Executive to continue to monitor this issue, the PR should provide a quarterly update concerning QMS improvements as indicated in the supplied action-plan. The first update should be supplied by 31 December 2011. **Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
(SLC T33b T36 T35 T34)	QMS is well maintained going forward.		
Staffing, resource and training issues were identified during the course of the inspection. (SLC T12 T15)	The PR should assess present resources versus activity, to ensure that enough appropriately trained and competent staff are in post to provide safe treatment services. The PR should forward a report to the inspector, giving details of such an assessment and any action points to be taken by 26 October 2011.	The PR states that a 'work activity matrix' was undertaken for laboratory services, which showed that adequate resources were in place in the laboratory to safely deliver the present level of treatment activity.	Although the PR has stated that there are adequate resources in place to safely deliver laboratory services, this process needs to be expanded to include all services provided, such as administrative and clinical services. The PR should forward documentation showing that adequate resources are in place within the administrative and clinical teams at the centre, in order to safely deliver the present level of treatment activities. To be forwarded by 31 December 2011. **Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The MBMS has not been reviewed or developed during the past eighteen months. (General Direction D0003)	The PR should ensure that data is retrieved from the centres database and used to review its present MBMS, prior to the updating of the strategy if required. A log of patients who were eligible for eSET, but who chose to have multiple embryos transferred should be updated and maintained. The PR should forward evidence to the inspector that the centre's MBMS has been updated, based on the review of its own data, by 26 October 2011.	The MBMS committee have reviewed the results for every cycle starting in 2010 where a woman is <37 but whom were eligible but said no and hence received 2 embryos, it was found that there were 10 such cycles. The committee amended the protocols and patient information and as such the revised protocol and information sheet is attached.	The PR has stated that an audit of all eligible eSET cycles started in 2010, where multiple embryos were replaced, has been undertaken and that subsequently both the patient information and MBMS have been revised to reflect the new data. The Executive to ensure that the centre's eSET log is examined during the next inspection. **No Further action required.**
During the review of the witnessing SOP, it was found that additional witnessing steps were required. (SLC T71)	The PR should ensure that the witnessing SOP is reviewed and amended to include areas highlighted within the report. Evidence that the SOP has been amended should be forwarded to the inspector by 26 October 2011.	Amended SOPs forwarded concerning all issues mentioned within the report.	The PR has supplied reviewed and amended witnessing SOPs for all issues mentioned within the report. To follow up at next inspection. **No Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Current donor payments are not compliant with General Direction D0001. (General Direction D0001)	The PR should ensure that donor payments are compliant with General Direction D0001. Evidence that the centre's procedure has been amended should be forwarded to the inspector by 26 October 2011.	Evidence that LFC's procedure has been amended is provided by the updated SOP LABPRO66 - Admin.SP.D.1. - Payment to donors. This will be reviewed again once the effective date is known for the recent changes to the donor compensation guidelines.	Procedure reviewed and amended in line with General Direction D0001. **No Further action required.**
Information submitted to the Registry via the EDI system was found to be inaccurate. (SLC T9e)	The centre should ensure that information submitted to the HFEA is accurate at all times. The centre should undertake an audit of the most recent information submitted to the register and liaise with the quality assurance officer at the HFEA to ensure that accurate information is sent/received going forward. Evidence that the process has been reviewed and amended should be forwarded to the inspector by 26 October 2011.	The process has been re-briefed to all staff. All current errors have been cleared via on-going communication with the HFEA Register team.	Issue resolved. **No Further action required.**

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
The present gamete/embryo transportation SOP does not include information on temperature, time limits or actions to be taken in the event of a shipment recall. (SLC T107 G15C)	The PR should ensure that the transportation SOP is reviewed and amended to include information relating to temperature and time limits, and actions to be taken in the event of a shipment recall. Evidence that the SOP has been amended should be forwarded to the inspector by 26 October 2011.	PR forwarded amended SOP.	Amended SOP still does not meet requirements of T107. Emailed PR with observations. PR to forward amended documentation by 31 December 2011. **Further action required.**
Some equipment SOPs reviewed do not include information concerning actions to be taken in the event of equipment malfunction. (SLC T27)	The PR should ensure that all equipment SOPs are reviewed and amended to include action points in the event of equipment malfunction. Evidence that all equipment SOPs have been reviewed and amended should be forwarded to the inspector by 26 October 2011.	The PR has supplied documentation relating to actions to be taken in the event of critical equipment malfunction and power failure.	Issue resolved. **No Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
When reviewed, the centre's website included inaccurate success rates. This was also an issue at the previous inspection (G4.2e).	The PR should ensure that all patient information displayed on their website is accurate and compliant with Chairs letter CH(11)02. Evidence that the website has been amended should be forwarded to the inspector by 26 October 2011.	The centre's website has been amended. It now has a direct link to the centre's success rates on the HFEA website.	Issue resolved. **No Further action required.**
During review it was discovered that some TPAs were not compliant with all required Licence Conditions. (SLC T116)	The PR should ensure that all TPAs are compliant with all required Licence Conditions. Evidence that all TPAs have been reviewed and amended should be forwarded to the inspector by 26 October 2011.	Reviewed TPA's supplied by PR.	The TPA's supplied are still not compliant with all Licence Condition requirements. PR to review and amend the TPA's by 31 December 2011. **Further action required.**
It was observed that equipment and premises cleaning records are not being updated (SLC T26).	The PR should ensure that cleaning records are accurately maintained. Evidence to be forwarded to the inspector by 26 October 2011.	The PR forwarded evidence that cleaning records were now being accurately maintained.	Issue resolved. **No Further action required.**

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Cryopreserved semen samples for oncology patients are not being divided into different cryo-storage vessels. (G17.7)	The PR should ensure that cryopreserved semen samples for oncology patients are divided into different cryo-storage vessels. The PR to forward an action-plan and time-line for this process to the inspector by 26 October 2011.	This task has been completed.	Issue resolved. **No Further action required.**

Additional information from the Person Responsible
The centre recognised that there would be few areas for improvement highlighted during the audit given the amount of change that had taken place in the last eighteen months, coupled with the integration of a new parent company that has established Quality Management and Corporate Governance Policies. The approach on the day of the inspection was very supportive and this was greatly appreciated by the senior management team, as is the ongoing support that the HFEA are providing to us.

HFEA Executive Licence Panel Meeting

18 November 2011

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

Minutes – Item 2

Centre 0088 – (London Fertility Centre) – Interim Inspection Report (Treatment & Storage) & Variation to change Licence Holder

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Ian Peacock, Analyst Programmer	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has undergone considerable organisational change over the past eighteen months, most notably the change of ownership, which occurred on 29 March 2010. The centre is now part of the Spire Healthcare group.

2. The Panel noted that there have been significant staff changes over the same time period, including a new laboratory manager, a new Person Responsible for research licence R0169, a new Licence Holder (LH) and a new Centre Manager.

3. The Panel noted that the Person Responsible (PR) is appropriately qualified and has successfully completed the PR Entry Programme.

4. The Panel noted that for the period of 2010-11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 26%.

5. The Panel additionally noted that on-going monitoring by the Inspectorate suggests that the centre's multiple clinical pregnancy rate is not likely to exceed the 2011-12 multiple birth rate of 15%.

6. Notwithstanding this assessment The Panel asked that the PR pay particular attention to this issue as the 2011\12 multiple births target is significantly lower than the centre's current performance.

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

8. The Panel noted that since the inspection the PR has implemented four of the major areas of non-compliance and four other areas of non-compliance or poor practice.

9. The Panel noted that the PR has given a commitment to implement the outstanding areas of non-compliance.

10. In considering the areas of non-compliance, the Panel had particular concerns regarding the relationship between staffing levels at the centre and the volume of activity. The Panel noted the PR's response to this, but endorsed the Executive Review requesting documentation by 31 December 2011 which demonstrated that adequate resources are in place to safely deliver the level of treatment planned.

11. The Panel noted that the Inspectorate recommend the continuation of the centre's licence with no additional conditions. This was subject to

the PR submitting a quarterly update to the Inspector, providing details of progress made.

Application for Variation of Licence Holder

12. The Panel noted that the centre had also made an application for the variation of Licence Holder (LH) for centre 0088. The application was for the treatment and storage licence and the research licence held by the centre.

13. The Panel noted that there have been two changes of LH involving all three London Fertility licences (L0088, L0308 and R0169), and these changes were approved by the Executive Licensing Panel on 28 July 2010 and 3 December 2010.

14. The Panel noted that the research project R0169 for centre 0088 is due to lapse on 31 December 2011.

15. The Panel also noted that an application for the variation of LH would be made shortly for centre 0308, London Fertility Centre (Storage).

16. The Panel noted that it was in receipt of a letter of resignation from the outgoing LH, Dr Brendan Ball, who is moving to take up employment at a different centre.

17. The Panel noted that it had received a letter of acceptance from the proposed LH, Mrs Melanie Proffitt, together with her CV detailing academic and professional qualifications and relevant work experience. The Panel noted that Mrs Proffitt is currently general manager at centre 0088 and therefore has a good working knowledge of the responsibilities associated with the position.

18. The Panel noted that all supporting documentation received from centre 0088, meets the satisfaction of the Inspectorate.

19. The Panel noted the Inspectorate's recommendation for the change of LH to Mrs Melanie Proffitt for both the treatment and storage licence and research licence for centre 0088.

Decision

20. The Panel endorsed the Inspectorate's recommendations:

- to continue the centre's licence, with no additional conditions and endorsed the recommendations made in the report; and

- to vary the centre's licence to make Mrs Melanie Proffitt the LH for the treatment and storage licence and the research licence held at

centre 0088, in accordance with section 18A of the HFE Act 1990 (as amended).

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