# HFEA Licence Committee Meeting

## 9 January 2014

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

### Minutes – Item 4

**Centre 0094 (Barts and The London Centre for Reproductive Medicine) - Interim Inspection Report Update**

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| Members of the Committee:<br>Andy Greenfield (lay) (Chair)<br>Bishop Lee Rayfield (lay)<br>Debbie Barber (professional)<br><br>Committee Secretary:<br>Lauren Crawford | Legal Adviser:<br>Sarah Ellson, Field Fisher Waterhouse<br><br>Observing:<br>Sam Hartley, Head of Governance and Licensing, HFEA |

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

The following papers were considered by the Committee:

- Executive update
- Interim inspection report 25 June 2013
- ELP minutes interim inspection report 23 September 2011
- ELP minutes interim inspection report 20 December 2011
- ELP minutes variation of a change of Person Responsible 1 June 2012
- ELP minutes variation of a change of Licence Holder 5 October 2012
- LC minutes interim inspection report 19 September 2013
- Audit summary from Person Responsible
- Correction to table in report (tabled)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

## Background

1. The Committee noted that an interim inspection report was considered by the Licence Committee on 19 September 2013. The initial report recommended that a condition be added to the centre's licence, that it suspend the commencement of new treatment cycles until such time that it could demonstrate that there were effective procedures in place for obtaining consent regarding to parenthood and the posthumous use of gametes. Also, that there are procedures for conducting a welfare of the child assessment before treatment is provided to any new patients.

2. After the report was submitted to the centre, in advance of September's meeting, the HFEA met with the PR and representatives of Barts NHS Trust. Further to that meeting an updated executive summary was submitted alongside the interim inspection report, which recommended that the Licence Committee adjourn the decision on the report findings for a period of approximately four months.

3. The Committee, after considering all of the above, agreed to adjourn its decision and urged the executive to continue to monitor the situation and comply with the recommendations within the report and to also provide updates on the progress of this situation.

## Discussion

4. The Committee noted the actions that have taken place since the last meeting. They noted that the PR has provided results of monthly audit reports regarding the completion of welfare of the child assessments (WOC) and consents to parenthood and posthumous use performed in September, October and November 2013. The Committee noted the correction to the report tabled at the meeting, and noted that it did not affect the recommendations within the report.

5. The Committee noted that the centre did not achieve 100% compliance in October and November in relation to completion of WOC assessments and, in addition, the consent decisions regarding the posthumous use of gametes and embryos in three cases were unclear.

6. The Committee noted that, although these reports demonstrate that the corrective actions have been largely effective and that there has been some improvement in the recording of consents, the Inspectorate still has concerns that the progress made is not being maintained.

7. The Committee further noted that the centre's team have also conducted an audit of the completion of legal parenthood consent for the period 2009 until the present. This audit has indicated significant historic failings in the documentation of consent relating to 14 patients. This was reported as an incident to the HFEA and is currently being managed through the incident report system.

8. The Committee noted that the executive recommends that the centre's licence should continue with no additional conditions.

9. The Committee noted that the Executive recommends that the Licence Committee should require the PR to continue to conduct and submit monthly audit reports. If any further significant decrease in performance is observed then this will be reported to the Licence Committee.

10. The Committee had regard to the fact that the current licence is due to expire in September 2014 and that the centre will therefore be subject to a full renewal inspection process later in 2014.

**Decision**

11. The Committee agreed to allow the continuation of the centre's licence with no additional conditions.

12. The Committee urged the PR to continue to conduct and submit monthly audit reports.

13. The Committee requested that the renewal inspection report should come before the Licence Committee in due course.

Signed: Date: 30/01/2014

Andy Greenfield (Chair)

# Interim Licensing Report

**Centre name:** Barts and The London Centre for Reproductive Medicine
**Centre number:**0094
**Date licence issued:**01/10/2009
**Licence expiry date:** 30/09/2014
**Additional conditions applied to this licence:** None
**Date of inspection:** 25/06/2013
**Inspectors:** Janet Kirkland (Lead), Sara Parlett and Lisa Beaumont
**Date of Licence Committee:19 September 2013**

## Purpose of the report

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

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

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

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

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

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

## Summary for the Licence Committee:

On the basis of the inspection findings recommendations for improvement were made in relation to five critical areas of non-compliance five major areas of non-compliance and three 'other' areas of non-compliance.

Following receipt of feedback from the Person Responsible in relation to these non-compliances the inspection team had continuing concerns as a consequence of which, a management review meeting was held on Monday 19 August 2013. The management review concluded that there may be an on-going risk to patients particularly in relation to consent and welfare of the child assessment. In consideration of the HFEA's Compliance and Enforcement Policy it was agreed that formal action was warranted.

On the basis of these concerns and in consideration that the responses provided by the Person Responsible have not provided reassurance that the non-compliances will be fully implemented in the prescribed timescale it is concluded that the PR has not discharged her duty under section 17 of the HF&E Act 1990 (as amended) (the Act) or ensured that the centres practices in relation to the conduct of welfare of the child assessments and the taking of consent are suitable.

Under section 18 (2) (b) of the Act the Authority may revoke a licence if it is satisfied that the person responsible has failed to discharge the duty under section 17. Section 18A (3) gives the Authority the power to vary a licence without an application under subsection (2) (i.e. on application by the PR or licence holder) if it has the power to revoke the licence under section 18(2). Section 18A (5) provides that the Authority may vary a licence without an application under this subsection by adding a condition to the licence.

Though as set out in the body of this report the evidence supports the revocation of the centre's licence under section 17(2) (b), the inspection team is satisfied that a more proportionate recommendation at this point is that a condition be added to the centre's licence. The inspection team therefore recommends that, under the powers provided by section 18A, a condition be added to the licence to suspend the commencement of new patient treatment cycles. The centre should not undertake any new patient consultations until the PR is able to demonstrate to that significant progress has been made in relation to implementation of the four critical areas of non-compliance set out below:

- **The PR should ensure that the provision of information to patients prior to giving consent is clear, and that the implications of such consent are discussed and documented clearly and consistently within the patient record.**
- **The PR should ensure that welfare of the child (WoC) assessments are performed and clearly documented within the patient record.**
- **The PR should ensure that, where relevant, patients are provided with information and counselling regarding consent to legal parenthood and that the relevant consents are clearly retained within the patient record.**

This condition will ensure that no treatment cycles are commenced before there are appropriate procedures in place to ensure that the welfare of any child born as a result of the

treatment is adequately considered and that there are procedures in place for obtaining effective consent.

There is also concern that the PRs response to the following recommendation lacked clarity:

- **The PR should ensure that gametes currently in store are being stored within their consented storage period.**

In imposing a condition that effectively limits activity it is anticipated that the centre will have an opportunity to make progress in fully implementing this recommendation.

The team made additional recommendations for improvement in relation to a further critical area of non-compliance, five major areas of non-compliance and three 'other' areas of non-compliance.

Since the inspection, the PR has implemented the following recommendations:

**Major areas of non compliance:**

- The PR should ensure that all areas, where confidential identifying information can be accessed, are secure at all times.
- The PR should ensure that information given to patients, prior to their consenting to the use of their embryos in training, explains whether any information will be fed back to them or not.

**Other' areas of practice that require improvement::**

- The PR should ensure that all relevant containers are labelled with the patient's/donor's full name and a further unique identifier.

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

**'Critical' areas of non-compliance:**

- **The PR should review the performance of the quality management system to ensure continuous and systematic improvement of the centre's practice's and the patient experience.**

**'Major' areas of non compliance:**

- The PR should gather and monitor patient feedback on their experience at the centre and take action to ensure that they are providing the highest quality of care.
- The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA.
- The PR should ensure that patient records are maintained in good order and that patient information including consents are filed securely in the relevant sections of the records.

**'Other' areas of practice that require improvement:**

- The PR should perform an audit to ensure that the procedures for provision of information and confidentiality and privacy comply with the approved protocols, the regulatory requirements and quality indicators.
- The PR should perform a risk assessment of the cryostore to ensure that it does not represent a risk to staff and cryopreserved material.

## Information about the centre

The Barts and The London Centre for Reproductive Medicine is located in London and has held a licence with the HFEA since1992.

The centre provides a full range of fertility services.

The centre provided 1,234 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30/04/2013.

In relation to activity levels this is a large centre.

## Details of Inspection findings

### Quality of Service

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

#### Outcomes[1]

HFEA held register data for the year ending January 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2012 the centre reported 423 cycles of partner insemination with 43 pregnancies. This equates to a10% pregnancy rate which is consistent with the national average.

#### Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 22%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to September 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was10%: this represents performance that is likely to produce a multiple birth rate that is statistically lower than the15% live birth rate target.

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

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

## Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; fertilisation check; embryo thaw; embryo disposal, active identification prior to sperm production and sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.

The inspection team was able to review records that were present in 10 sets of patient notes and concluded that records of witnessing are accurately maintained.

## Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by ten patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in eight of the ten files reviewed. Of the two records where discrepancies were identified one patient was not registered on the HFEA database. For the other discrepancy, the patient had given consent to contact research and had left the remaining consent options blank. This however had been reported incorrectly to HFEA as the patient not consenting to any contact.

See recommendation 8.

## Consent: To the storage of cryopreserved material

On the day of the inspection a review of the centre's database indicated that all embryos in storage are being stored with effective consent. It was however observed that sperm samples for 407 patients are currently being stored beyond their consented storage period: for some samples consent to storage expired as far back as 2001. The PR has implemented a robust bring forward system for embryo storage and a suitable member of staff has been identified to take responsibility for rolling out this same system for the sperm samples in storage. The PR is confident that this will be completed by the end of 2013.

See recommendation 1.

### Staffing

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

The centre has had several key staff changes including change of PR, LH and QM, The PR had worked closely with the inspector to address on-going issues however it was evidenced on inspection that were still significant areas of concern regarding non-compliances which had been identified on the previous inspection in 2011.

Due to the current shortfall in the number of medical staff, the centre is using locum doctors and has reduced the number of cycles per week to 25. The inspection team noted that centre staff were attending a team-building day on 27 June 2013.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out that day. However patient feedback to the HFEA highlights a number of cases where patients reported having difficulties contacting the centre, in and out of hours and delays to their appointment times.

Staff in the laboratory were observed as being able to carry out their activities without distraction, and were available to carry out witnessing activities when required.

### Patient experience

During the inspection visit, no patients agreed to speak with the inspection team. Forty - nine patients provided feedback via questionnaires directly to the HFEA in the time since the last inspection,11 patients commented that they have compliments about the care that they received, and 19 commenting that they had complaints; the HFEA has however not received any formal written complaints from patients since the previous inspection.

The negative feedback centred around three key themes:

- Difficulties in contacting the centre (by phone and email)
- Attitude of staff in general
- General communication and information provided to patients, particularly around drug treatment, administration and the provision of out of hours contact numbers.

On the day of inspection, the inspection team observed a staff/patient interaction where they considered the staff member's attitude to be inappropriate. This was also witnessed by the PR who agreed with the inspection team's observation.

See recommendation 6.

## Monitoring of the centre's performance

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

## Compliance with HFEA standard licence conditions

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

1. Prior to giving consent to use of embryos in training the gamete providers are not given information as to whether information will be fed back to them.
   See recommendation10.
2. In the last two years, the centre has not audited how far procedures for provision of information and confidentiality and privacy comply with the approved protocols, the regulatory requirements and quality indicators.
   See recommendation 12.
3. It was observed on inspection that patient files retained in the reception area could be accessible to unauthorised persons.
   See recommendation 7.
4. The inspection team considered that the cryostore was cramped and it was difficult for staff to manoeuvre around the dewars. Centre staff confirmed that this had been raised as an issue and solutions were being discussed. The inspection team is concerned that this room may not be adequate for the centre's activities and may pose a safety risk to staff.
   See recommendation 13.
5. Whilst performing an audit of patient consent to disclosure the inspection team became concerned regarding the general maintenance and content of patient records.
   The following issues were noted:
   a) Missing consents for legal parenthood
      See recommendation 4
   b) No evidence of appropriate welfare of the child assessments
      See recommendation 3
   c) Discrepancies with the patient checklist (consents, test results and provision of information) at the front of the notes with what was actually present in the notes. For example, checklist at the front of the patient's notes implied that consents and tests results were completed however there was no evidence found in the files.
      See recommendation 9
   d) Loosely and poorly filed documents within the notes, such as consent forms. This could result in documents being lost or misfiled with the consequence that staff may be unable to assess whether the patient has provided consent or not.
      See recommendation 9
   e) Two instances where the patients had not consented to the use of gametes/embryos after death but had consented to posthumous birth registration. See recommendation2.
6. At egg collection not all containers (dishes, vials, ampoules, tubes etc.) used during the procurement of eggs are labelled with the patient's/donors full name and a further identifier or a uniquely identifying donor code.
   See recommendation 11.

7. Containers used during the processing and procurement of eggs, sperm and embryos are only labelled with the patient's initial, surname and uniquely identifying code, rather than the patient's full name and uniquely identifying code.
   See recommendation 11.

## Compliance with recommendations made at the time of the last inspection

Following the interim inspection on 21 June 2011, recommendations for improvement were made in relation to four areas of critical non-compliance, six areas of major non-compliance and 13 'other' areas of non-compliance.

The PR had provided information and evidence that all of the recommendations were fully implemented prior to the current inspection. However observations and a records audit performed on the day of the inspection raised concerns regarding the effectiveness of corrective actions and on-going monitoring by the PR of the following non-compliances identified in 2011:

- The PR should take immediate action to ensure patient and partner welfare of the child assessment forms are properly completed and that they are subjected to appropriate review by staff and appropriate follow-up actions are taken where necessary.
- The PR should ensure there is a formal process for regular periodic review of the performance of the quality management system.
- The PR should audit the consent to disclosure of identifying information from the HFEA register held in patient records against the consent data submitted to the HFEA via the EDI; any discrepancies should be corrected. The PR should ensure that in future all data submitted through the EDI system regarding consent to disclosure of identifying information from the HFEA register is entered accurately.

Following the 2011 inspection, the PR forwarded to HFEA summaries of audits relating to these non-compliances. However, on the basis of the findings of this inspection the inspection team considered the corrective actions identified following these audits were not effective. For example, following the recommendation in 2011 that the PR should ensure welfare of the child assessments are completed, the centre audited their practices but continues to identify non-conformities. In addition, the inspection team observed a missing welfare of the child assessment in one record in addition to incomplete assessments. It is therefore the inspection team's opinion that the centre does not have a process in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement.

See recommendation 5.

## On-going monitoring of centre success rates

In 2012, the centre did not receive any requests from the HFEA to review procedures for the provision of treatment with reference to success rates.

## Provision of information to the HFEA

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

The centre is broadly compliant with register submission requirements.

**Annex 1**

# Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

## ‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| 1. On the day of the inspection a review of the centre’s database indicated that sperm samples for 407 patients are currently being stored beyond their consented storage period(Schedule 3, 8(1) HF&E Act 1990 (as amended)). | The PR should provide the HFEA with an update on the number of patients whose sperm remains in storage without effective consent by the time this report is considered by Licence Committee. Also by the time this report is considered by Licence Committee, where gametes remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre’s intended actions and the anticipated timescale for their implementation. The PR should provide monthly updates to the HFEA on progress | On the day of the inspection 407 patients samples were highlighted as being out of their written consent period. On review of the database on 2nd August 2013 the following was found:<br>• Fertility Frozen Back-up storage – of 540 freeze events, 15 events were outside of the storage consent period for 12 patients.<br>• Oncology Sperm Banking – of 1340 freeze events, 295 events were outside of the | Due to the lack of clarity in the response to this critical area of non-compliance the inspector is not reassured that the PR has recognised the seriousness of this issue.<br><br>The PR should clarify the number of patients for whom gametes are being stored without effective consent and provide a detailed action plan as to how this will be addressed including timescales as requested. |

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| | in implementing the proposed actions.<br>The PR is reminded of guidance issued by the HFEA in CH(03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.<br><br>By 1 January 2014. | storage consent period for 136 patients.<br>• Surgical Sperm Retrieval – of 189 freeze events, 25 events were outside of the storage consent period for 23 patients.<br>• Known donor / surrogate storage – of 24 freeze events, 2 events were outside of the storage consent period for 2 patients.<br>• Of the 2,094 freeze events, 337 events are outside of the storage consent period for 173 patients.<br><br>During 2013 to date;<br>394 Freeze events discarded for 222 patients.<br>65 freeze events discarded on patient request before expiry.<br>329 freeze events discarded as without effective consent.<br>We envisage that this process will be completed by the end of 2013.<br><br>The number of samples without effective consent is now key performance indicator recorded | **Further action needed.** |

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| | | on the CIP and HFEA Fertility Dashboard from July 2013.<br><br>Copy included with this report. | |
| 2. It was noted in two records reviewed on inspection that the patients had not consented to the use of gametes/embryos after death but had consented to posthumous birth registration.<br><br>(SLC T57 and T58). | The PR should ensure that provision of information to patients prior to giving consent to the use of gametes/embryos after death and to posthumous birth registration is clear. The implications of such consents must be discussed and it should be ensured that the consents documented, are consistent and accurately reflect the patient's wishes.<br><br>Actions to implement this recommendation should be taken immediately, and we expect the centre to provide a summary of actions taken by 5 September 2013.<br><br>The PR should perform an audit of a representative sample of patient consents to the use of gametes/embryos after death and to posthumous birth registration to | Consents<br>1. Awaiting further clarification form HFEA regarding the posthumous use and naming as legal father on birth of child follow death. 02/08/2013<br>2. Planned audit of sample of patient consents in week commencing Monday 2nd of September for review and recommendations submitted by 5th September. | The PR has advised that the completion of consent forms to indicate posthumous birth registration was intentional and was expected to allow birth registration in the event of death of a male partner after commencement of treatment rather than in the event of the provision of treatment after death.<br><br>The HFEA has clarified that these consent forms are not intended for this purpose and is concerned that if patients have not consented to the use of gametes/embryos after death but have indicated in the consent forms that they consent to posthumous birth registration they may be under the erroneous impression that there are gametes/embryos in store and that they may be |

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| | ensure that they are consistent. In addition the PR should review the processes for providing information prior to consent.<br><br>The PR should provide the inspector with a copy of the audit results by 25 December 2013. | | able to use them in the event of the death of their partner.<br><br>The impact of this is dependent on whether patients were adequately informed of the purpose of the consent before being asked to give the consent. The PR should seek legal advice on whether the consents provided by patients were provided after the provision of enough information to ensure the consents are effective.<br><br>If it is concluded that the consents to posthumous birth registration are not effective then the PR should perform an audit of all records where patients have gametes or embryos in store and review all of the relevant consents to identify where consents are not effective. All relevant patients should be contacted to advise them of the error and new consents should be obtained if relevant. |

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| | | | The PR should ensure that all staff are informed and competent in the use and purpose of all consents forms used at the clinic and that they are consistent in the discussions and advice given to patients.<br><br>The PR should provide the HFEA with a summary of the legal advice obtained by the centre and, if relevant, the outcome of the audit of patient consents and an action plan documenting the anticipated timescale for contacting any affected patients.<br><br>The PR should provide the inspector with evidence of staff training and of competency assessments in information giving prior to obtaining consent.<br><br>The executive considers that this area unless corrected immediately with significant |

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| | | | improvement in compliance is an impediment to the delivery of a safe service.<br><br>It is concluded that the PR may have failed to ensure that consents obtained are effective and that as a consequence, may have failed to ensure that suitable practices are used in the course of the activities as required by section 17(1)(d) of the Act and that the conditions of the centre's licence have been complied with as required by section 17(1)(e) of the Act. |
| 3. A sample of patient records reviewed on inspection did not contain appropriate records of WoC assessments.<br><br>It was not clear whether the assessments had been performed but the record of the assessment | The PR should ensure that WoC assessments are performed for all patients attending for licensed treatment.<br><br>The PR should undertake an audit of patient records to identify whether the inspection observations represent a systemic failure or a rare occurrence. A | WOC Consent -<br>1. An audit undertaken in July 2013 has shown an increase in the completion of the centre's page of the form that confirms that the assessment has been completed.<br>2. Senior Managers are to review the process for taking and reviewing this consent and the | The inspector has reviewed the audit results.<br><br>Whilst it is acknowledged that completion of the welfare of the child assessments has improved and that corrective actions including the provision of staff training and a review of the process by senior |

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| was missing or whether the assessments had not been completed.<br>(SLC T56). | summary report of the audit findings including an indication of the number of patient's affected by the omission, corrective actions and the timescale for their implementation should be submitted to the inspector by 25 September 2013. | point at which it needs to be done and by whom.<br>3. Agreement that a stamp (red) will be made for the first page of the clinical notes where the presence and completion of both WOC and CD forms will be documented. These have now be ordered 13/08/13. | management it is of some concern that the audits continue to indicate non-compliance with this requirement.<br><br>The executive consider that this area unless corrected immediately with significant improvement in compliance is an impediment to the delivery of a safe service.<br><br>It is concluded that the PR may have failed to ensure that the welfare of any child born as a result of treatment has been adequately assessed and that as a consequence, may have failed to ensure that suitable practices are used in the course of the activities as required by section 17(1)(d) of the Act and that the conditions of the centre's licence have been complied with as required by section 17(1)(e) of the Act.<br><br>**Further action needed** |

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| 4. A sample of patient records reviewed on inspection did not contain appropriate consents to legal parenthood.<br><br>The inspection team were unclear if the consents had been obtained or were missing from the records.<br>(SLC T60) | The PR should undertake an audit of patient records to identify whether the inspection observations represent a systemic failure or a rare occurrence.<br><br>A summary report of the audit findings including an indication of the number of patient's affected by the omission, corrective actions and the timescale for their implementation should be submitted to the inspector by 25 September 2013.<br><br>The PR should ensure that in future, where relevant, patients are provided with information and counselling regarding consent to legal parenthood and that copies of the relevant consents are retained within the patient record. | Consents -<br>1. Legal Parenthood. New pre-treatment checklists are now in place listing the necessary forms for treatments involving donor sperm ,embryos created from donor sperm and donated embryos.<br>2. Preliminary audit of LP undertaken in July 2013 after the inspection. A repeat audit to be undertaken in September 2013 and submitted to the HFEA as requested. | As only one record was included in the preliminary audit of patients receiving donor gametes the inspector is not satisfied that this audit was representative of practices in recording consent to parenthood.<br><br>The executive consider that this area unless corrected immediately with a significant improvement in compliance is an impediment to the delivery of a safe service.<br><br>It is concluded that the PR may have failed to ensure that consents obtained are effective and that as a consequence, may have failed to ensure that suitable practices are used in the course of the activities as required by section 17(1)(d) of the Act and that the conditions of the centre's licence have been complied with as required by section 17(1)(e) of the Act. |

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| | | | **Further action needed** |
| 5. The inspection team is not satisfied that the centre has processes in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement<br><br>(SLC T32) | The PR should take immediate action to establish and implement a process for reviewing the performance of the quality management system to ensure continuous and systematic improvement.<br><br>A plan documenting the action to be taken to ensure compliance with quality management system requirements and the timescale for their implementation should be submitted to the HFEA by the time this report is considered by Licence Committee.<br><br>The PR should provide monthly updates to the HFEA on progress in implementing proposed actions. | i. During 2012 – 2013 the Quality Management System has been developed under the guidance of an external ISO expert with experience of setting up a robust QM system for fertility clinics.<br>ii. The first Management Review Meeting for the QM System will take place in September 2013.<br>iii. The ISO inspection dates are now set; Stage 1 – 9th October 2013 and Stage 2 – November 2013 date to be confirmed by SGS.<br>iv. A copy of the audit schedule for 2013 is included with this report. | The inspector has received the audit schedule.<br><br>The inspector acknowledges the PR's intention and actions towards establishing a robust quality management system.<br><br>There remains significant concern as to the implementation of any quality management system and the adherence of staff to established policies and procedures.<br><br>The inspector looks forward to receiving monthly updates on progress in implementing proposed actions.<br><br>**Further action needed** |

### ‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| 6. Patient feedback submitted to the HFEA via patient questionnaires and observation of a staff patient interaction on the day of the inspection resulted in a degree of concern regarding<br>• provision of patient information<br>• staff attitude<br>• difficulties in contacting the centre | The PR should with immediate effect seek patient feedback, to assess the patient experience including:<br>• provision of patient information<br>• staff attitude<br>• communication<br><br>The PR should audit the results and provide the inspector with a copy of the findings including corrective actions and timescales.<br><br>By 25 September 2013<br><br>The PR should further investigate patient feedback relating to difficulties in contacting the centre by e-mail and | 1. Patient questionnaires will be circulated in August 2013. Audit of patient satisfaction survey to be undertaken in final week of August 2013.<br>2. A new patient questionnaire has been designed to assess the patient experience . A copy of this has been included with this report. | The inspector has received the copy of the questionnaires and looks forward to receiving a copy of the audit being performed in August.<br><br>The inspector encourages the PR to act upon the issues raised in the inspection event including communications issues and staff attitude with immediate effect. |

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| | telephone and perform a further assessment of the patient experience following the completion of any corrective actions.<br><br>By 25 December 2013. | | The inspector looks forward to receiving a copy of the audit results by 25 September 2013.<br><br>**Further action needed** |
| 7. Access to areas where confidential identifying information can be seen or obtained is not restricted to people authorised by the PR. On the day of the inspection it was noted that patient files retained in the reception area could be accessible to unauthorised persons. (HF&E Act 1990 (as amended) section 33A). | With immediate effect, the PR should ensure that all areas where confidential information is held are secure at all times.<br><br>The HFEA should be advised of the actions taken to implement this recommendation by the time this report is considered by Licence Committee. | 1. Notes collected ready for weeks scan lists stored in grey cabinet will be moved into the next office.This move has now been completed 09/08/13.<br>2. No notes will be left in the reception area overnight. Completed 09/08/13.<br>3. Patient records will not be left within reaching distance of the desk during operational hours. Completed by 09/08/2013. | The inspector is satisfied with the response.<br><br>**No further action.** |
| 8. Discrepancies were found between two patient/partner | The PR should audit procedures for submitting patients' consent to disclosure | 1. Compentency assessment of current | The inspector looks forward to receiving |

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| disclosure consents on patient files and the related consent data submitted by the centre for inclusion on the register.Guidance supplementary to Chairs Letter CH (10)05 and Direction 0007.<br><br>This was identified as an area for improvement at the time of the previous inspection. | to researchers to the HFEA. A summary report of the findings of the audit including corrective actions and the timescale for implementation of the corrective actions should be submitted to the HFEA by 25 September 2013.<br><br>Three months after the implementation of corrective actions the centre should audit a random sample of ten patient records to ensure that the consent to disclosure decisions taken from patients have been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months.<br><br>A summary of this audit should be submitted to the HFEA by 25 December 2013. | EDI data entry personnel to be undertaken.<br>2. Audit of patient records against EDI entry. | evidence of competency assessments and training in addition to the results of the audit by 25 September 2013.<br><br>**Further action needed** |
| 9. A sample of patient records reviewed on inspection were not maintained in good order and documentation pertaining to the patients including consents were not filed securely in the relevant section of the records (SLC T47). | The PR should ensure that patient records are maintained in good order and that patient information including consents are filed securely in the relevant sections of the records.<br>The PR should perform an audit of patient records to ensure that they are in good order. | Notes<br>1. All teams are now required to file all papers in the relevant section of the notes and not use the pockets, even in the short term<br>2. New patient folders | The inspector acknowledges the response and looks forward to receiving the results of the audit by 25 December 2013.<br><br>**Further action needed** |

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| | The PR should provide the inspector with a copy of the audit results including corrective actions by 25 December 2013. | are now being ordered that do not have a pocket.<br>Checklists -<br>1. Copies of consent forms should and will be found filed in the relevant section of the notes.<br>2. Not all blood results will be present in the notes as they are viewed on CRS (electronically) rather than hard-copy.<br>3. Checklist completion and accuracy will be audited and reviewed by the Senior Management Team and audited as per HFEA request. | |
| 10. The patent information regarding the use of embryos in training does not include information as to whether information will be fed back to them (SLC 97). | The centre should ensure that prior to giving consent to use of embryos/gametes in training the patient information includes whether information will be fed back to them. | This has now been added to the Information session slide and the IVF consent.<br>02/08/2013. Copy | The inspector has received the amended consent form and is satisfied with the response. |

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| | The inspector should be provided with a copy of the amended patient information by 25 September 2013. | included. | **No further action.** |

### ‘Other’ areas of practice that requires improvement

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

| Area of practice and reference | Action required and timescale for action | PR Response | Inspection team’s response to the PR’s statement |
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| 11. In the last two years, the centre has not audited how far procedures for provision of information and confidentiality and privacy comply with the approved protocols, the regulatory requirements and quality indicators (SLC T36). | The PR should provide the HFEA with an audit schedule documenting all activities to be audited and an anticipated timescale for completion of the audit programme by the time this report is considered by Licence Committee. The PR should provide quarterly updates to the HFEA on progress in implementing the planned audit schedule. It is recommended that audits are prioritised on the basis of risk.<br><br>The first quarterly up-date should be received by 25 September 2013. | Plan to review the process for the provision of information and confidentiality in August to September 2013. Copy of audit schedule included with this report. | The inspector is satisfied with the response and looks forward to receiving the first quarterly update by 25 September 2013.<br><br>**Further action needed.** |
| 12. On inspection it was noted that the cryostore appeared very cramped and it was difficult for staff to manoeuvre around the dewars. | The inspection team acknowledges that this may fall outside of the HFEA’s remit. However, we are concerned about the impact this finding could have on centre staff and gametes/embryos. | Due to the number of LN2 dewars and filling tank in the dedicated cryostore there is limited space for manoeuvre.<br>1. Review dewar positioning | The inspector is satisfied with the response and looks forward to receiving a copy of the risk assessment by 25 |

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| (Code of Practice Guidance 17.2 (a)). | The PR should undertake a risk assessment to ensure that the cryostore does not represent a risk to staff or to the cryopreserved material, and report the findings to the centre's inspector by 25 September 2013. | within room. This has been completed and the space is now easier to move around in and safer to perform the storage and removal of samples.<br>2. Continue to remove stored sample form dewars at end of consented storage period.<br>3. Produce a risk assessment of space and hazards with a view to extending area of cryostore (room 4). | September 2013.<br><br>**Further action needed.** |

| Additional information from the Person Responsible |
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