HFEA Executive Licensing Panel Meeting

15 November 2013

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

Minutes – Item 1

Centre 0314 – (The Leeds Centre for Reproductive Medicine) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Joanne Anton – Policy Manager	**Observing:**
David Moysen – Head of IT	Sam Hartley – Head of Governance and Licensing

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 is a large centre, licensed by the HFEA since January 2010, which provides a full range of fertility services.

2. The Panel noted that the centre is currently on a four-year licence due to expire on 13 December 2015 and that the inspection took place on 21 August 2013.

3. The Panel noted that for the year ending 30 April 2013, HFEA held register data show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

4. The Panel noted that for the year 2012, the centre reported 144 cycles of partner insemination with 25 pregnancies. This equates to a 17% pregnancy rate which is consistent with the national average.

5. The Panel noted that in 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represented performance that was likely to be statistically lower than the 20% live birth rate target for this time period.

6. The Panel noted that 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 was 11%. This also represents performance that is likely to be statistically lower than the 15% live birth rate target for this time period.

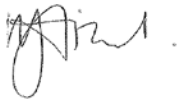
7. The Panel noted that at the time of inspection, five major and five other areas of non-compliance were identified. The Panel noted that the PR has made steps towards improvements and is committed to implementing the recommendations.

8. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

9. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued.

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



Signed: Date: 28 November 2013

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: The Leeds Centre for Reproductive Medicine
Centre number: 0314
Date licence issued: 14/12/2011
Licence expiry date: 13/12/2015
Additional conditions applied to this licence: None
Date of inspection: 21/08/2013
Inspectors: Parvez Qureshi (Lead) and Sara Parlett
Date of Executive Licensing Panel: 15/11/2013

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 Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence.

The team has made recommendations for improvement and these should be implemented within the time specified.

The Executive Licensing Panel is asked to note that there were no recommendations for improvement in relation to 'critical' areas of non-compliance, five 'major' areas of non-compliance and five 'other' areas of non-compliance:

In providing feedback on this report the Person Responsible (PR) provided evidence that the following recommendations have been implemented:

'Other' areas of practice that require improvement:

- The PR should consider the risks of not labelling the tubes/dishes used during egg collection.
- The PR should ensure that the findings of the audit for selecting and recruiting donors are documented and appropriate action taken.
- The PR should review practice to ensure that payments made to donors are compliant with HFEA requirements.

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

'Major' areas of non compliance:

- The PR should ensure that audits are conducted for all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence.
- The PR should with immediate effect seek patient feedback, to assess the patient experience including contacting the centre via telephone, waiting time delays and staff attitude.
- The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent.
- The PR should review procedures for submitting patients' consent to disclosure to researchers decisions to the HFEA.
- The PR should ensure that patients privacy and confidentiality is not compromised and access to areas where confidential identifying information can be seen or obtained is restricted to people authorised by the PR.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's website meets the requirements of Chair's Letter CH (11)02.
- The PR should take immediate action to ensure that procedures are established to identify when additional screening may be indicated and to develop procedures for carrying out additional screening testing.

Information about the centre

The Leeds Centre for Reproductive Medicine is located within the Leeds Teaching Hospitals NHS Trust and has held a licence with the HFEA since January 2010.

The centre provides a full range of fertility services.

The centre provided 2005 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to July 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 30 April 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 144 cycles of partner insemination with 25 pregnancies. This equates to a 17% 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 13%. This represented performance that was likely to be statistically lower than the 20% live birth rate target for this time period.

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 was 11%. This also represents performance that is likely to be statistically lower than the 15% live birth rate target for this time period.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre has been proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. However, the HFEA's on-going monitoring of the

[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.

centre's clinical multiple pregnancy rate in the time since the commencement of the 10% multiple birth rate target in October 2012, suggests that if the rate continues at current levels then the clinic may be unlikely to meet the current rate. It is suggested that the PR should review the centre's strategy to meet the HFEA's current 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 and sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing/manual system. The inspection team was able to review ten sets of patient notes and concluded that records of manual witnessing are maintained. The centre does not maintain a copy of the electronic witnessing records in the patient notes, but these can be accessed electronically. A review of one such set of records demonstrated that appropriate electronic witnessing records are also 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 10 patients and their partners were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in six of the records reviewed. In two sets of records the patients had consented to disclosure to researchers but this had not been reported accurately to the HFEA. In the other two sets of records the patients had not consented to disclosure to researchers and this also had not been reported accurately to the HFEA. See recommendation 2.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that one set of embryos were being stored beyond the expiry of the consented storage period by approximately three months. Although the bring forward system appeared robust and centre staff were aware of these embryos, they had not been discarded due to the notes going missing. The laboratory staff confirmed that the centre was actively trying to locate the notes and that without these they could not accurately follow their procedure for allowing embryos to perish. In addition, one set of sperm (due for disposal) was in storage for which ten years storage had expired two month prior to this inspection and the laboratory staff were unable to confirm whether the sample had been discarded or not.

The centre has oncology samples which have been in storage for more than ten years where it is not clear if appropriate consent is in place. However, since 2012 the centre has been conducting a review of the oncology samples to ensure they are in storage with effective consent, audit reports for this were made available for the inspection. See recommendation 1.

It was also noted during the course of this inspection that the centre had two further sets of embryos in storage without consent from one gamete provider where the cooling off period had been invoked appropriately.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 45 patients also provided feedback directly to the HFEA in the time since the last inspection. Approximately 30% of the individuals providing feedback commented that they had compliments about the care that they received. A majority of the comments identified from the feedback received in which the centre could make improvements were contacting the centre via telephone, waiting time delays and staff attitude See recommendation 4.

Patients privacy and confidentiality is not fully maintained at the reception. During the inspection, we observed interactions of patients with reception staff and conclude it was easy for conversations of a confidential nature to be overheard by others in the reception area. This theme was also identified in feedback from patients that we received. The staff reported that they have recognised this and are looking into it further via conducted surveys. Also during the course of the inspection it was noted that a set of notes were left unattended on a filing cabinet in a corridor outside of a consulting room with no restricted access to the corridor from the waiting room. See recommendation 5.

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 and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- At egg collection not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier. See recommendation 6.
- A review of the success rates on the centre's website was conducted and was found to be non-compliant with HFEA guidance. The website does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type. See recommendation 7.
- The findings of the centre's audit for selecting and recruiting donors have not been documented. See recommendation 8.
- Where the centre compensates donors an excess amount the centre does not keep:
    - a record of the actual excess expenses incurred by the donor, a record of the amount reimbursed to the donor and the receipts produced by the donor, and/or the steps taken by the PR to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred. See recommendation 9.
- In the last two years, the centre has not audited how far some licensed activities or activities carried out in the course of providing treatment services that do not require a licence comply with the approved protocols, the regulatory requirements and quality indicators. See recommendation 3.
- HTLV-I antibody testing is not performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas, or if their

parents originate from those areas. Also in appropriate circumstances the centre does not carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi). See recommendation 10.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in August 2011 recommendations for improvement were made in relation to two areas of major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that three of the recommendations were fully implemented within the prescribed timescales.

Following the last inspection the PR gave a commitment to fully implement the following recommendations:

- The PR should ensure the accuracy of data provided via the EDI system regarding consent to the disclosure of identifying information to researchers.
- The PR should establish QIs or objectives relevant to all activities and conduct regular audits for them.

However, it was noted during this inspection that these had not been fully implemented (see recommendations 2 and 3).

On-going monitoring of centre success rates

In the last year, the centre has received the following five risk tool alerts in relation to IVF, ICSI and FET:

Pregnancy rate per cycle - fresh, stimulated, ICSI-only, patient eggs <38 (twice)
Pregnancy rate per cycle - fresh, stimulated, IVF-only, patient eggs <38 (twice)
Pregnancy rate per cycle - frozen, IVF and ICSI, patient eggs < 40

Over the past year an on-going dialogue with the PR to address issues with success rates has taken place. The PR has been proactive in reviewing practice to ensure these issues are addressed.

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.

Currently this centre is broadly compliant with register data 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
None			

‘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
1. On the day of the inspection one set of embryos and one set of sperm were in storage past their consented period (HF&E Act 1990 (as amended), Schedule 3, 8(1) and 8(2)). This was identified as an area for improvement at the time of the last inspection. The centre has oncology samples which have been in storage for more than ten years but a register or database to record the date of expiry of the 10 years was not kept accurately.	The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent by the time this report is considered by an ELP. Also by the time this report is considered by an ELP, where gametes and embryos 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 in implementing the proposed actions. Summary reports of the findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 21 November 2013. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and	We have been conducting an audit process resolving issues as found for all patients with sperm stored for >10 years since January 2012. This is continuing work in progress. We hope it demonstrates the enormity of effort being made by the PR & Lead embryologist in trying to resolve the historical pre-merger issues retrospectively.	A review of the submitted information confirms that the centre has addressed the issue regarding effective consent being in place for the storage of one set of embryos and one set of sperm (the issues with oncology samples remain outstanding – see below). The PR has provided an update on all patients with sperm stored for more than ten years together with an action plan to ensure all historical sperm in storage has effective consent for storage. It is acknowledged this is work in progress, however, the PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.

	a summary report of the findings of the audit should be provided to the HFEA. 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.	There have been significant difficulties as a large proportion of patients fail to respond. We have to confirm everyone's address with National Tracing Agency's and have been sending registered letters. There are also a large number of untracked notes from pre-merger era waiting to be filed. This has meant delay in access to the notes. As of today, we still are looking for the notes of 9 patients. We would like HFEA's advice regarding 2 categories of non responder cancer patients: 1**.** who we know are alive, whose address has been checked with National Tracing Agency, whose HFEA consent has expired but who are failing to respond to written communications. 2. a small number of non-responder patients have expired HFEA consent but their trust consent is still in date and hence	The PR to update the centre inspector regarding untracked notes. The centre inspector will work with the PR to explore how these issues can be resolved. Further action required

		legally valid.	
2. The records of consent to disclosure to researchers given by 10 patients and their partners were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in six of the records reviewed. In two sets of records the patients had consented to disclosure to researchers but this had not been reported accurately to the HFEA. In the other two sets of records the patients had not consented to disclosure to researchers and this also had not been reported accurately to the HFEA. Guidance supplementary to Chair's Letter CH (10)05 and Direction 0007. This was identified as an area for improvement at the time of the last	The PR should review procedures for submitting patients' records of consent to disclosure to researchers to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the actions should be submitted to the centre's inspector, by 21 November 2013. Three months after the implementation of any changes, the PR should conduct an audit of consent to disclosure to researchers to ensure the changes are effective and a summary report of the findings of the audit should be provided to the HFEA. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application is made by researchers for the release of that information.	1. An audit is already underway. We plan to check 10% notes of patients registered this year along with the database and EDI forms so that we can identify patterns and source/s of error. 2. We have already undertaken a review training of our nursing team so that risk of such errors is minimised. 3. We have asked our database programmer to introduce prompts for these data fields that are already mandatory for completion so that staff are asked to check accuracy of data input before EDI submission. 4. We will revisit the content of all our standard audits to ensure that they meet current regulatory requirements and issues that are identified outside the audit. A report of the audit will be submitted as requested in November 13.	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this recommendation. Further action required

inspection.			
3. In the last two years, the centre has not audited how far some licensed activities, or activities carried out in the course of providing treatment services that do not require a licence comply with the approved protocols, the regulatory requirements and quality indicators. SLC T36.	The PR should ensure that audits are conducted for all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence. At the time the PR responds to this report, the PR should provide the HFEA with a schedule documenting the anticipated timescale for completion of these audits. It is recommended that audits are prioritised on the basis of risk. The PR should provide monthly updates to the HFEA on progress in completing these audits. A copy of the final audit reports are to be provided to the HFEA by 21 February 2014.	Our standard audit process began in April 13. This is also a large piece of organised multi-disciplinary annual activity and I enclose a report for an update	Following review of the submitted information, the lead inspector considers this to be an acceptable response. The PR to provide a copy of the final audit reports to the HFEA by 21 February 2014. Further action required.
4. Patient feedback submitted to the HFEA via patient questionnaires and the patient feedback on the day of the inspection resulted in a degree of	The PR should with immediate effect seek patient feedback, to assess the patient experience including contacting the centre via telephone, waiting time delays and staff attitude.	We recognise the issues that patients have raised with yourselves, some of which we were aware of and had been trying to rectify, whilst others we will address in the future. For	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this

concern regarding contacting the centre via telephone, waiting time delays and staff attitude	The PR should audit the results and provide the centre inspector with a copy of the findings including corrective actions and timescales. By 21 February 2014. The PR should further investigate patient feedback relating to difficulties in contacting the centre by telephone and perform a further assessment of the patient experience following the completion of any corrective actions. By 21 May 2014.	many years, I as the PR have been asking for anonymous feedback from each and every couple treated in our unit by asking them to complete a questionnaire for us. This is because I take 'patient experience' seriously and constantly strive to improve on the quality of service that we provide. Our 'Patient Satisfaction Questionnaire' objectively measures patient's score for our service in different departments and is computed every quarter for comparison. Our aim has been to obtain a balanced majority feedback, which on balance has been quite good as you would see and in the past we have achieved a response rate of >80%.	recommendation. Further action required.
5. Patient privacy and confidentiality is not fully maintained at the reception area. Patients are able to overhear other patient's conversation with the reception staff (this issue was also highlighted in the patient feedback).	The PR should ensure that patients privacy and confidentiality is not compromised and access to areas where confidential identifying information can be seen or obtained is restricted to people authorised by the PR. Immediately.	At the time of development, our reception area was designed along the lines of 1. We have tried to create a one way system to avoid patients standing behind each other or crowding over the receptionist 2. We intend to see if a glass enclosure for the reception can be created to avoid patients	The lead inspector considers this to be an acceptable response and it is at the centre's discretion how these privacy and confidentiality issues are resolved. This will be subject to review at the time of the next

A set of notes were left unattended on a filing cabinet in centre corridor outside a consulting room with no restricted access to the corridor from the waiting room. SLC T43.		standing behind each other in audible distance. 3. We are looking at various options by which notes can be left for the consultant during the course of the clinic so that they are secure or in possession of a licensed person. 4. The doctors have been advised to bring the notes back to the administrative offices themselves at the closure of the clinic.	inspection. However, the PR to inform the centre inspector on progress being made to address this recommendation. Further action required.

‘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
6. At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier. SLC T101.	While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not labelling the tubes used during egg collection. The HFEA should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by the time this report is considered by the ELP.	We have performed a risk assessment in this regard. As ONLY ONE egg collection happens at one time and the next is NEVER begun until the gametes have been put away, the risk of labelling the tubes is deemed greater than working in the manner that we do.	The lead inspector considers this to be an acceptable response. No further action required.

7. A review of the success rates on the centre's website was conducted and was found to be non-compliant with HFEA guidance. The website does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type. Chair's Letter CH (11)02.	The PR should ensure that the centre's website meets the requirements of the Chair's Letter CH (11)02. By 21 November 2013.	The unit's database has been in need for significant improvements and this has prevented the PR from conducting the relevant analysis as well as monitoring the KPIs in an ideal manner. However the trust IT department is now working on this project and has provided the reassurance that the required work will be completed by Oct -Nov13 and this the PR expects will enable the detailed analysis as required by HFEA in a reliable manner	The lead inspector considers this to be an acceptable response. The PR to inform the centre inspector on completion of this recommendation. Further action required.
8. The findings of the audit for selecting and recruiting donors have not been documented. SLC T36.	The PR should ensure that the findings of the audit for selecting and recruiting donors are documented and appropriate action taken. Evidence that this action has been completed should be sent to the centre inspector by 21 November 2013.	An audit has been performed that confirms that consents, registration, counselling and screening is taking place in line with SOP. We have also recently amended our SOP with regards to initial consultation following which donor selection by a consultant, screening and counselling takes place. This will be a subject of the next audit	Following review of the submitted information, the lead inspector considers this to be an acceptable response. No further action required.
9. Where donors are compensated an excess amount the centre does not	The PR should review practice to ensure that payments made to donors are compliant with the	The practice of compensating donors has been reviewed. I can confirm that we have never	The lead inspector considers this to be an acceptable response.

keep: a record of the actual excess expenses incurred by the donor. a record of the amount reimbursed to the donor. the receipts produced by the donor, and/or the steps taken by the PR to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred. General Directions 0001.	terms prescribed in Directions 0001. The PR should inform the HFEA of how this practice has been reviewed and change implemented by the time this report is considered by the ELP. Three months after the implementation of any changes, the PR should conduct an audit of donor payment records to ensure the changes are effective. The PR is to provide a summary report of this audit to the HFEA when completed.	compensated any male or female donor above the HFEA guidance. We have records of all expenses issued. All male donors provide signatures of receipt and these are duly filed. The record of reimbursement for male donors' is kept and the list has been reviewed to confirm that no male donor has received more than permitted with in Code of Practice.	No further action required.
10. HTLV-I antibody testing is not performed if the gamete provider lives in or originates from high-incidence areas or has sexual partners originating from those areas, or if their parents originate from those areas. Also in appropriate circumstances the centre does not carry out additional testing	The PR should take immediate action to ensure that procedures are established to identify when additional testing may be indicated and to develop procedures for carrying out additional testing. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by an ELP. Within three months of the implementation of procedures, the	The entire policy for screening patients and donors for viral and microbiological infections is being reviewed currently by the PR with advice from the Lead Consultant Virologist and Consultant in Infectious Diseases at this trust.	The lead inspector considers this to be an acceptable response. The PR to provide a copy of the final policy for screening to the HFEA by 21 January 2014. Further action required

depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi). SLC T50(c) and (g).	centre should conduct an audit of screening and a summary report of the findings of the audit should be provided to the HFEA.		

Additional information from the Person Responsible