Inspection Report

Date of Inspection: 13 and 20 October 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 16 hours
Inspectors: Gill Walsh and Stephanie Gadd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 13 August 2009 and 21 February 2012.

Date of Executive Licensing Panel: 9 March 2012

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	St Jude's Hospital
Centre Number	0198
Licence Number	L0198/7/a
Centre Address	St Jude's Women's Hospital 263 Penn Road Penn Wolverhampton WV4 5SF
Person Responsible	Mr Jude Harris Adeghe
Licence Holder	Dr Chaman Lal
Date Licence issued	01/02/2010
Licence expiry date	31/01/2014
Additional conditions applied to this licence	None

Contents

Page

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

St Jude's Women's Hospital is an independent gynaecology and assisted conception unit housed within a large converted residential property located on the outskirts of Wolverhampton. The centre currently provides approximately 200 licensed treatments per year. The centre provides fertility services to both self – funding and NHS patients.

The centre has been licensed by the HFEA since January 2002 and has a satellite agreement with the centre's sister unit, St Jude's Hospital, Newcastle-under-Lyme.

St. Jude's Women's Hospital is open seven days per week for treatment and consultation from 7:30am to 7pm weekdays, 8am to 4:30pm on Saturdays and 10am to 3pm on Sundays.

This interim inspection was conducted over two days, one week apart. The inspection was continued on a second day because information brought to light during a records audit prompted further exploration of traceability and confidentiality systems and processes.

The Person Responsible (PR) for the centre is registered with the General Medical Council (GMC) and has been on the GMC specialist register for Obstetrics and Gynaecology since 1996. Mr Adeghe has been PR at the centre since it was first licensed and has successfully completed the HFEA Person Responsible Entry Programme (PREP), he is also the medical director and quality manager for the centre.

The centre was last inspected on 13 August 2009 for licence renewal following which a treatment and storage licence was granted for four years without additional conditions. There have been no applications received to vary the centre's licence since this time.

Activities of the Centre:

Type of treatment	**Number of treatment cycles for the period 01/09/2010 – 31/08/2011**
In vitro fertilisation (IVF)	36
Intra cytoplasmic sperm injection (ICSI)	80
Frozen embryo transfer (FET)	17
Intra uterine insemination (DI)	1
Intra uterine insemination – partner (IUI) 01/01/2010 – 31/12/2010	Nil
Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Outcomes*
For IVF/ICSI, HFEA held register data for the period April 2010 to March 2011show the centre's success rates are in line with national averages across all age ranges. The centre did not perform any partner IUI procedures during 2010.

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

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three critical areas of non-compliance, four 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 that the following recommendations have been fully implemented.

Critical areas of concern:

- **Witnessing - Practice should be revised to ensure that all critical steps in the processes described are appropriately witnessed and that all positive identification and witnessing steps undertaken are documented on the witnessing record, the original of which should be retained with the patient's medical record. The status of the person performing the process and the person witnessing it should also be recorded.**
- **Traceability - The centre must immediately establish, implement and comply with documented procedures to ensure that:**
  a. all gametes and embryos, and
  b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.
- **Consent - The centre should establish documented procedures to obtain written informed consent and ensure that all staff who participates in any element of the process are trained and assessment for competence in seeking consent and ensuring that the information and documentation provided to the person(s) giving consent is correct and that the documents are completed appropriately. The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented.**

Major areas of non compliance:

- **Witnessing** - All witnessed elements of the sperm preparation process should be recorded. As part of their risk assessment for sperm preparation (and only for sperm preparation), the PR and senior embryologist may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it.

Other areas of practice that require improvement:

- **Adverse incident reporting** - The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises. The procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:
  a. all relevant available information about suspected serious adverse events and reactions, and
  b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.
- **Legal parenthood-** A written procedure should be established to ensure that should a woman being treated vary or withdraw her consent to the nominated second parent, the nominated second parent is informed of this change in writing. The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented.

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

Major areas of non compliance:

- **Storage of gametes and embryos** - The centre should review their current practice to ensure that the 'bring forward' system is effective in alerting the centre to contact patients with gametes or embryos in store in sufficient time to make an informed decision regarding the continued storage or otherwise of their stored material. The centre should conduct a comprehensive audit of storage consent records held in the laboratory against the consents recorded in the patient's primary medical record. The findings of the audit and corrective actions required should be documented and submitted to the centre's inspector.
- **Record keeping and document control** – The centre should review their documented procedures for managing data and information to ensure that there is an organised and unified system in operation throughout the centre for the accurate and consistent recording of information and that all patient/donor records required for full traceability are complete and retained in an accessible form for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.
- **Confidentiality and privacy** - The centre should review their SOP for maintaining confidentiality to ensure that all patient and donor related information is held securely and only disclosed in circumstances permitted in law. The SOP should

document the systems in place to prevent the unauthorised disclosure of information while guaranteeing the traceability of gamete, embryo or tissue (cell) donations. The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented. The centre should ensure that appropriate quality indicators relevant to the maintenance of confidentiality are established and the procedures for maintaining the confidentiality of donors and the traceability The findings of the audit and corrective actions required should be documented and submitted to the centre's inspector.

Other areas of non compliance:

- **Equipment and materials** - Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure. All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available. The PR should submit an action plan listing the critical equipment that is to be mapped and the anticipated timescale for completion of the validation to the HFEA.
- **Procedure for the recall of gametes or embryos -** The centre should ensure that before the centre distributes gametes and embryos there are procedures in place that define the responsibilities and actions required when a distribution is recalled and a procedure for investigating the recall as an adverse incident.
- **Validation of laboratory processes** - All critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient.
- **Welfare of the child -** Quality indicators relevant to welfare of the child assessment procedures should be established and an audit conducted to assess how far welfare of the child procedures comply with approved protocols, regulatory requirements and quality indicators.
- **Quality management - audit** - The PR should review the centre's audit processes to ensure that they are effective in monitoring compliance with the regulatory requirements, own protocols and quality indicators as required by standard licence conditions.

The inspection team would like to note the positive response made by the Person Responsible in acknowledging the potential seriousness of the critical non compliances and his commitment, both verbally during and in writing immediately following this inspection, to work swiftly to take corrective actions and implement robust systems to ensure compliance going forward. The inspectorate will remain in close liaison with the centre team in achieving this.

The inspection team recommends the continuation of the centre's licence without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

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** Before treatment, storage or both are offered, staff at the centre provide the person seeking treatment or storage, and their partner (if applicable) with a costed treatment plan tailored to their needs. The plan details the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The subject is discussed at the first consultation and an itemised list of proposed treatment and costs is provided to the patient. Four patient records were seen to contain detailed plans. Patient(s) interviewed at the time of inspection stated that they had sufficient information about their treatment costs and had been afforded time to consider and discuss this with staff. (Guidance 4.3) **Parenthood** Treatments with donor sperm and oocytes are provided to patients and their partners who are married or in civil partnerships and to patients and their partners (if applicable) who are not. In discussion, the PR demonstrated an understanding of the requirements for documenting parent and intended second parent consents and the requirements of standard licence conditions T60, T61 and stated that it was the norm that he would be the person leading this discussion and consent process with patients and their partners. He also described that the importance of informing any resulting child at an early stage that they were born as a result of such treatment would be discussed. The PR described the measures that would be taken to ensure treatment was not provided to any woman in the event that there was any variation to or withdrawal of consent to parenthood. (Standard licence condition T64).
What they could do better. **Parenthood** One patient record reviewed on inspection was found to contain an incomplete and incorrectly completed consent to legal parenthood form. The woman being treated had completed the form intended to be completed by the proposed second parent. There was no corresponding form completed by the second parent in the records. This consent error was brought to the attention of the PR and it was agreed that the couple would be contacted to inform them of this. When the inspection team returned on the second date, the PR reported that the couple had been contacted and the missing second consent was in their possession in error and that it would be returned to the centre. Although the PR fully described the process by which patients and their partners having

treatment with donor gametes or embryos are informed about parenthood laws and consent is sought, the centre does not have established written procedures to manage this process and ensure appropriate written records of consent to parenthood are obtained prior to a woman affected by parenthood laws being treated with donor sperm or embryos. (Standard licence condition T33(b))

The centre does not currently have procedures in place to ensure that in the event that a woman being treated withdraws or varies her consent to the nominated second person being the legal parent of any child born, the originally nominated second parent is informed of the change in writing. (Standard licence condition T65)

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

What the centre does well.

As part of the consent taking process, patients and their partners are asked to consider whether they agree to information about their treatment held on the HFEA register being disclosed to researchers if requested and to record their consent or that consent to this is withheld, in writing on the HFEA consent to disclosure (CD) form. (Guidance Note 5.27d) Patient(s) interviewed confirmed that this was the case in their experience.

The person responsible demonstrated an awareness and understanding of the compliance requirements related to disclosure of information on the HFEA register for use by researchers. As part of the consent audit conducted on inspection, five sets of patient and partner records were audited against electronic records held by the HFEA. The consent decision recorded in the patient / partner records held at the centre correlated with that held electronically by the HFEA in all cases. (Directions 0005, paragraphs 8 and 9 and standard licence condition T9 (e)).

The centre's own audit of consents in place for all gametes and embryos stored conducted in August 2011 demonstrated that there is written, effective consent in place for the storage of all cryopreserved gametes and embryos currently in store.

An audit of five patient records on inspection demonstrated that written consent is in place for the storage of gametes and embryos relating to the records seen.

The senior embryologist stated that the centre has not had to initiate the 'statutory cooling – off period' to date but that there was a mechanism in place to initiate this in the event that there is a dispute between gamete provides regarding the continuation of storage of their embryos. (Act, Schedule 3 4A(4)

What they could do better.

The centre's policy is that all gamete providers should consent to one year storage of their gametes or embryos in the first instance and are then asked if they wish to extend this time subsequently. The senior embryologist stated that the embryologists monitor this by noting the consent period on related laboratory work sheets held in the laboratory and maintain a

separate record of consents extending storage after the initial one year period.

When conducting the patient consent audit on inspection, a number of anomalies were noted when comparing the main patient / partner medical records against records held in the laboratory. In one instance the consent records for a couple with embryos in store indicated that one gamete provider gave consent to storage for 10 years but the second gamete provider's consent present indicated one year only. The corresponding record held in the laboratory indicated 10 years for both gamete providers. Whilst it is recognised that valid consent from both gamete providers is currently in place as the embryos have been stored for less than one year to date, the inspectors felt that this system of monitoring effective consent and consent to the extension of storage is not robust. The record keeping system appears to be somewhat fragmented and the consent records held in the laboratory and noted on the laboratory database did not appear to always accurately reflect what was held in the main patient / partner medical record.

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 21%[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to meet the target/performance at a statistically significant level, 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% (Standard licence condition T123)

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

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

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

Patients are informed of the risks associated with multiple pregnancy at the clinical consultation and are given the opportunity to discuss their suitability for elective single embryo transfer (eSET) with the consultant and with the embryologist during their patient journey up until the time of embryo transfer when patients are advised as to the quality of their embryos. Patient(s) interviewed at the time of inspection explained that the risks of multiple pregnancy and multiple births had been discussed prior to providing consent and treatment and that they had been provided information for consideration. An audit of the written patient information showed that all the requirements of guidance (Guidance 7.5 a, b, c and d) had been included.

The senior embryologist was able to demonstrate that quality indicators relative to the efficacy of the centre's multiple birth minimisation strategy have been developed and are monitored and discussed at monthly unit meetings as part of the quality management system. (Standard licence conditions T35 and T36) Centre staff maintain a summary log of all cases in which multiple embryos have been transferred to patients who meet the criteria for eSET, the reason for which was seen to have been recorded in each case. In medical records seen, it was noted that the risks of multiple pregnancy had been discussed with the patient and where eSET was declined or not clinically indicated, note was also made in the patient record.

Centre staff were also able to demonstrate that a summary log which conforms to the requirements of Directions 0003 is kept recording any instance whereby three embryos are transferred into any woman, this record is signed by both the PR and senior embryologist and the rationale is recorded in the patient's medical record.

What they could do better.
Nothing noted at inspection.

Validation of critical equipment and processes

What the centre does well.
Staff at the centre provided documented evidence showing that all existing critical equipment has been validated. (Standard licence condition T24) Staff maintain a log which records equipment maintenance history and which will also include revalidation following repair. The senior embryologist stated that no repairs to key equipment have been required within the last two years. One new incubator was all so seen to have been validated. (Standard licence condition T25)

Documented evidence showed that instruments used for the procurement of gametes and embryos are validated and regularly maintained. Equipment and consumable materials in use are all CE marked. (Standard licence condition T30) Logs of regular cleaning, maintenance, calibration and routine servicing are maintained. (Standard licence condition T28)

Staff provided documented evidence to show that laboratory critical processes have been validated. The PR described that all clinical procedures are conducted in accordance with Royal College of Obstetrics and Gynaecology Society and National Institute of Clinical

Excellence (NICE) recommendations. (Standard licence condition T72) The PR participates in peer review appraisal by the Licence Holder for the centre and an assisted reproductive medicine consultant colleague at a local NHS hospital in line with the GMC Good Medical Practice Framework for Appraisal and Revalidation, which includes clinical audit of procedures and outcomes of treatment.

What they could do better.

The scientific inspector noted that validation documents for certain critical temperature sensitive equipment used in the preparation and incubation of gametes and embryos did not include temperature mapping to demonstrate that there are no significant temperature inconsistencies (hot or cold spots) within the piece of equipment.

Following a review of documents and discussions with the senior embryologist, the scientific inspector considered that the laboratory processes validation completed to date is more representative of an audit of practice against prescribed standard operating procedures and not validation of the process itself.

Witnessing

What the centre does well.

All samples and the patients or donors to whom they relate are identified and witnessed contemporaneously by two members of staff at all critical points of the clinical and laboratory process with the exceptions detailed below. A record of the witnessing steps observed is retained in the patient record. (Standard licence condition T71)

It was not possible to observe witnessing practice on the day(s) of inspection, therefore this requirement was assessed by discussion with staff, a review of documentation and an audit of witnessing records.

The centre's witnessing SOP was seen; it lists the occasions when a witness is required and states the need for witnesses to be trained. (Standard licence condition T33(b))

Four members of staff are trained in witnessing (two of which are the embryologists and two are nurses). There is a master list of staff signatures on file. The witnessing record is signed and the time and date of the procedure is noted.

In the event that there is only one embryologist on duty, the senior embryologist stated that a nurse witnesses the process. Witnessing has been audited by the centre (for the last three years) by assessment of laboratory records contained within 10 sets of randomly selected patient records. The most recent audit reports were reviewed on inspection and recorded 100% compliance. (Standard licence condition T36)

Competence in witnessing has not been carried out as a separate assessment; however compliance with processes which involve witnessing has been evaluated for each embryologist. (Standard licence condition T15(a))

What they could do better.

The status of the staff member is not included in the witnessing record. This requirement was discussed.

During the notes audit at the time of inspection it became apparent that there was no documented evidence of contemporaneous witnessing for some of the critical steps in the processing of gametes and embryos, specifically:

- Sperm preparation – there are two steps involving gamete transfer. Witnessing is documented at the initiation of sperm preparation, but the witness is not present at the time of the second transfer from the density gradient tube to the final wash tube.
- Denuding of oocytes prior to ICSI – no documentary evidence of this step being witnessed.
- Embryo transfer – witnessing of patient identity is documented by the embryologist and a witness, but the identification of the corresponding embryo (dish label) is not. The embryologists stated that a second person witnesses the embryos being loaded into the catheter, however there was no documentary evidence of this.
- These observations suggest that the centre's witnessing audit procedures are not fully compliant with the requirement of standard licence condition T36 that trained and competent persons must audit the activities authorised by the licence against compliance with the regulatory requirements.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre actively recruits egg donors and egg sharers but does not actively recruit sperm donors.

There are processes and practices in place for gamete and embryo donation that are compliant with Directions 0001 and related Standard licence conditions were detailed below.

There is an SOP in place for the process to be followed when selecting and recruiting donors. (Standard licence condition T33(b).

The senior nurse at the centre confirmed that quality indicators relative to donor recruitment have been established which are measured against as part of the donor audit process. The most recent donor audit was conducted in 2010. (Standard licence conditions T35 and T36)

The medical records for one egg donor and one egg sharer were viewed on inspection.

An audit of both sets of patient records showed both women had undergone all required donor screening investigations (standard licence condition T52 and that the screening had

been conducted by a Clinical Pathology Accreditation (CPA) (UK) accredited laboratory. (Standard licence condition T53(a)) All parties had been given appropriate information (standard licence condition T58) and the opportunity to receive proper counselling about the implications of being treated with, sharing or donating their gametes or embryos. (Standard licence condition T60)

Documented evidence was provided to show that the egg donor had received reimbursement restricted to expenses incurred in the UK for travel and child care costs incurred during the donation cycle which were within the limits prescribed in Directions 0001 and that the egg sharer received her own treatment within the same treatment cycle. (Directions 0001) The senior nurse described the process by which the centre is mindful to maintain the confidentiality of patients who are egg sharing or receiving shared eggs in the clinical setting. Documentation seen in the egg sharers' and egg recipients' notes gave clear direction as to the terms of these arrangements.

The centre has imported one embryo only since the last inspection which was compliant with Directions 0006.

Where sperm samples are transferred from other licensed centre's within the UK there is a mechanism in place to monitor that the 10 family limit is not breached and that the supplying centre is informed of donor usage outcomes.

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

What they could do better.

As part of the witnessing, consent and donor screening audit of patient / donor records conducted on inspection, a number of issues regarding the traceablility of donor gametes and the organisation of patient / donor records came to light are described in the section areas of concern.

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

What the centre does well.

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

What they could do better.

Embryo testing (if applicable)

What the centre does well.

This centre does not conduct embryo testing.

What they could do better.

2. Changes / improvements since the previous inspection on 13 August 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
For the 12 month period up to 13 July 2009, the average time taken to pay HFEA invoices was 57 days.	The PR should continue to ensure that the HFEA invoices are paid within 28 days of the date of the notice.	**No further action required.** The finance department of the HFEA report an improvement in the timeliness of payment since the last inspection and currently report no issue with the payment of treatment fees.
Laboratory staff reported that there are occasions when there is only one embryologist in the lab and therefore witnessing is not always conducted contemporaneously.	The PR should ensure that there is sufficient trained staff to conduct witnessing checks and that witnessing takes place at the time of the clinical or laboratory process/procedure and recommendations should be implemented immediately with written assurance provided to the HFEA by 13 October 2009. **19 October 2009:** Written assurance was provided by the PR and was documented in appendix C on the renewal report.	**No further action required**. From documentation seen and discussions with staff on inspection, the inspectors were assured that two trained people are available to witness processes contemporaneously.
There was no evidence of a documented procedure being in place for the witnessing of sperm preparation.	The centre should have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process, including sperm preparation. This recommendation should be implemented immediately and written assurance provided to the HFEA by 13 October 2009. **Update 19 October 2009:** A documented procedure for witnessing of sperm	**No further action required**.

Area for improvement	Action required	Action taken as evidenced during this inspection
	preparation was received by the HFEA.	
One case of severe ovarian hyper stimulation syndrome (OHSS) was not reported to the HFEA as an adverse event. Section 17(1)g of the HFE Act (as amended) Licence Condition T120 Directions 0011	The PR should ensure any incidence or suspected incidence of OHSS which required hospital admission is reported to the HFEA through the established incident reporting mechanism within the prescribed time scales.	**No further action required**. The trigger point for reporting OHSS was discussed with the PR on inspection and the inspector was assured that the occurrence of any episode of severe OHSS requiring the patient to be admitted to hospital would be reported to the HFEA.
At inspection, although there was evidence of servicing and maintenance, there was no evidence of critical equipment or process validation.	The PR should ensure that all critical equipment and technical devices are identified and validated.	**Further action required**. Please see the section on validation.
It was observed on inspection that screened donor sperm samples were being stored in an unscreened tank with samples from patients who have been partially screened.	The PR should ensure that storage facilities are provided that clearly separate and distinguish gametes and embryos prior to release/ in quarantine from those that are released and those which are rejected, in order to prevent mix up and cross contamination. The PR should assess the risks of cross contamination of the screened donor samples that have been stored in a dewar with partially screened material. The result of the assessment should be documented and any corrective actions should be implemented to minimise the risk of future cross contamination. Patients should be informed of any risks identified. The	**No further action required** Following risk assessment and validation of this practice, the centre continues this practice. .

Area for improvement	Action required	Action taken as evidenced during this inspection
	HFEA should be advised of the findings of the assessments and any actions taken as a result of the assessment by 13 November 2009. **Update 19 October 2009**: The PR provided written confirmation that an extensive literature search and consultation with Consultant Microbiologists confirm that there is no risk of cross contamination.	
Two sets of patient records seen on inspection contained inaccurately recorded consent documents.	The PR should ensure that patient/donor consent is properly documented and conduct an audit to of consents in place to ensure the forms accurately reflect the consent provided by the patients/partners and donors. The PR should ensure all staff who seen consent have had training in how to seek consent using the HFEA consent forms effective from 1 October 2009. A summary report of the audit findings and any required corrective actions and a timeline for implementation should be provided to the HFEA by 13 November 2009.	**Further action required**. The centre was proactive in ensuring the consent forms were corrected and copies were provided to the inspectorate on 1September 2009. On 19 October 2009 the PR provided written confirmation that a consent audit had been completed and would be continued a monthly basis. However, in the course of the inspection, an audit of patient consent records identified that consent to legal parenthood was incorrectly completed in one record seen. These observations suggest that the centre's consent audit procedures are not fully compliant with the requirement of standard licence condition T36.

Area for improvement	Action required	Action taken as evidenced during this inspection
		Please see relevant section of this report.
In one set of notes, it was observed that a patient consented to the posthumous use of embryos created using her gametes but was not screened as a donor.	The PR should ensure that patients consenting to the posthumous use of embryos created using their gametes are screened in accordance with standard licence conditions with immediate effect. A copy of an amended consent form was received by the inspectorate on 1st September 2009, showing that the patient no longer consents to the posthumous use of the embryos created using her eggs.	**No further action required** relating to this occurrence.
There was no evidence that the new counsellor had completed an induction or initial training programme.	The PR should ensure that the counsellor retrospectively and that all new staff are provided with an appropriate induction to the centre.	**No further action required**. The PR stated that all new staff have received induction training, this was confirmed in discussion with an embryologist recently recruited to the team.
Documentation submitted pre-inspection indicated that the most recent laboratory audit was carried out between 23 June 09 and 5 July 09. There were no discrepancies noted. However, in the course of the records review the inspection team noted that the consent form related to the stored donor sperm did not indicate the storage period.	The PR should ensure that the storage of gametes is in accordance with relevant patient consent and that storage audits include a review of the consented duration of storage. It was recommended that the reason for the failure to identify that sperm was being stored without properly documented consent is investigated and that procedures are subject to corrective action if required.	**Further action required.** An audit of patient records on inspection identified a number of anomalies regarding the recording of patient storage consents. These observations suggest that the centre's consent audit procedures are not fully compliant with the requirement of standard licence condition T36. Please see the relevant

Area for improvement	Action required	Action taken as evidenced during this inspection
	A summary report of the findings and any required corrective actions and a timeline for implementation should be provided to the HFEA by 13 November 2009. **Update 19 October 2009**: The PR provided written confirmation to the HFEA that the centre has conducted a consent audit to ensure that consent forms and storage of gametes are all in line and in order. The audit was carried out in September and will be on-going on a monthly basis.	section of this report.
Patient records observed at inspection contained evidence of witnessing but in some instances the time and date of the witnessing check had not been recorded.	A record should be made in the patient/donor notes at the time the procedure takes place confirming the date and time of the procedure.	**No further action required in relation to his recommendation but further action required relating to witnessing**.
The procedure for responding to the low oxygen alarm required evacuation only after 10 minutes or more of the alarm sounding.	Laboratory staff reported that should the oxygen depletion alarm go off unexpectedly, the procedure is to vacate the area immediately and wait for the warning light before re-entering the lab. This should be documented in the procedure.	**Further action required.** On inspection the senior embryologist confirmed that should a low oxygen alarm sound when not a test, the area would be evacuated immediately the SOP seen does not reflect this.
The centre's quality management system had been further developed since the last inspection and the PR reported that a quality management review/evaluation will be conducted by the end of the year.	The PR should ensure that a regular review of the centre's quality management system and all its services is conducted.	**No further action required**. The PR stated and documentation reviewed in the course of the inspection confirmed that a review of the quality management system had been conducted.

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 into 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
GN 8 Welfare of the Child 1.4 Has your centre audited how far WOC procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?[see T36] SAQ = no	The centre has not established quality indicators or audited their welfare of the child procedures and documentation with the last two years.	**Further action required.**
GN 15: Procuring, processing and transporting gametes and embryos 2.6 Does your centre have a procedure for the investigation of any recall as an adverse incident [CoP interpretation of mandatory requirements 15B) SAQ = no	The centre rarely if ever distributes gametes or embryos from the centre and has not had cause to investigate a recall of distributed gametes or embryos. In the event that this was required, the centre's clinical incident policy would be enforced. This policy does not directly reference investigation following a recall but does guide the investigation of an incident.	**Further action required.**

GN 19 Traceability Traceability of donated gametes and embryos used in treatment. **GN 30 Confidentiality and privacy** Potential breach of confidentiality and privacy of donors. **GN 31 Record keeping and document control** Failure to maintain robust systems for the management of medical records which ensures that all records are clear and readable and protected from unauthorised amendment and retained and readily retrievable.	As part of the standard patient records audit (consent to treatment / donation / storage / screening / witnessing) conducted on inspection, a number of egg share recipient / egg sharer and donor egg recipient and egg donor records were matched and 'mapped' through the patient / donor treatment pathway. During this audit it became apparent to the inspectors that there is a significant degree of variation in how donor information has been recorded to ensure traceability of donor gametes used in the treatment of a recipient. Information was seen to be recorded in several different ways and in several different locations examples of which were: • in several cases the donor code was not recorded in the recipient's primary medical record or in laboratory records; instead a 'cycle code' (the month and year of egg collection) was noted on the embryo transfer laboratory sheet which could only be interpreted by the senior embryologist when asked to determine which egg donor the record related to. and lack of clarity regarding how easily	**Further action required**

Cont.	• in one instance seen, the donor's full name and date of birth was written on the recipient's embryo transfer laboratory sheet which was retained within the patient's primary medical record. • in instances where the donor code was not recorded in the recipient's medical record or on the laboratory sheet it was only possible to trace the egg donor where a copy of the HFEA treatment cycle registration form was present in the recipient's medical record. • The centre's records management policy does not specify the retention schedule for medical and laboratory records or the confidentiality requirements of Section 33 of the HFE Act 1990 (as amended). Examination of these and further files prompted the inspectors to cross reference patient treatment and donor records in the audit sample with records held on the register at the HFEA.	

	Simultaneously, centre staff were asked to locate information that could not be readily found by the inspectors in recipient medical or laboratory records made available to the inspectors. Following a lengthy and detailed 'mapping process' collating information held in the laboratory and / or in the medical records against information held by the HFEA registry department, it was determined that all donor information could be traced to the relevant treatment cycles recorded with the HFEA. The inspection team did however conclude that; • the centre' s record keeping and documentation systems are not robust and represent a significant risk to the traceability of treatment and donor information by members of the centre team and representatives of the HFEA who require access to this information at the centre. • Medical records were disorganised and information was being held in	

	different locations and was not easily accessible to all parties who may legitimately require this information. • the centre's records were not clear, easily readable or protected from amendment and could not be readily retrieved when required. • information recorded within some medical records presented a potential and significant risk to the maintenance of the privacy and confidentiality of donors • there was no evidence provided to indicate that: o training and assessment of competence had been conducted for gamete traceability procedures o the centre's traceability SOP does not specify how and where donor information is to be recorded to ensure traceability of donor gametes used in treatment o the centre could not demonstrate that they have procedures in place to ensure	

	that all required records are accurate, protected from unauthorised amendment, retained and readily retrievable when requested.	

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
GN 18 Witnessing Contemporaneous witnessing of the step whereby oocytes are denuded prior to ICSI is not documented. Embryo transfer – patient identity is signed for by the embryologist and a witness, but the identification of the corresponding embryo (dish label) is not. The embryologists stated that	Witnessing practice should be revised to ensure that all critical steps in the processes described are appropriately witnessed and that all positive identification and witnessing steps undertaken are documented on the witnessing record, the original of which should be retained with the patient's medical record. The status of the person performing the process and	This has been taken on board and corrected. A new witnessing sheet has been created and now in use.	No further action required.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
a second person witnesses the embryos being loaded into the catheter, however there was no documentary evidence of this. (Standard licence condition T71)	the person witnessing it should also be recorded. **Action to be implemented immediately.**		
GN 19 Traceability The systems and documentation currently in place to ensure the traceability of donor gametes and donor information either in laboratory records or the donor recipient's primary treatment records are inconsistent and not robust. Standard licence conditions T99,T100, T102	The centre must immediately establish, implement and comply with documented procedures to ensure that: a. all gametes and embryos, and b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa. These documented procedures must include the following information: a. the unique and accurate	The SOP is being revised as are the relevant laboratory forms to achieve full compliance. Not yet completed due to christmas holidays. Should be completed by 31st January 2012. Audit will be carried out and completed by 30 March 2012.	The PR requested an extension to the deadline for completing the SOP which was agreed by the executive. The PR has subsequently confirmed that this has been done. Progress with the audit will be monitored.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	identification of each patient/donor b. the unique and accurate identification of each set of gametes and embryos These written procedures must be communicated to all relevant staff and their competence assessed in this procedure. **The PR should submit evidence to the HFEA of how these actions have been implemented by 29 December 2011** The centre should ensure that quality indicators relative to the traceability of donors and donor gametes used in treatment are established and audited against. The findings of the audit and corrective actions required should be documented and submitted to		

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	the centre's inspector. **Actions to be completed by 30 March 2012**		
GN 5 Consent **GN 7 Legal Parenthood** One patient record reviewed on the first day of inspection was found to contain an incorrect and incomplete consent to legal parenthood form. The centre does not have a written procedure in place for obtaining the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos. (Standard licence conditions T15(a) and T33(b))	The centre should establish documented procedures to obtain written informed consent and ensure that all staff who participates in any element of the process are trained and assessment for competence in seeking consent and ensuring that the information and documentation provided to the person(s) giving consent is correct and that the documents are completed appropriately. The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented. **Action to be completed by**	SOP is being finalised and should be completed by 31 January 2012.	Since inspection the PR has confirmed that the relevant corresponding consent form has been returned to the centre by the couple in question and that the patient record is now complete. The inspection team are confident that the centre has learned from this instance and will ensure that this situation does not recur. The PR requested an extension to the deadline for this which was agreed by the executive. The PR has subsequently confirmed that this recommendation has been implemented.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	29 December 2011.		

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
GN 18 Witnessing The status of the practitioner and the witness is not recorded. Contemporaneous witnessing of some elements of the sperm processing procedure is not being documented. (CoP guidance 18.4(c)) (Standard licence condition T71)	The status of the participants should be recorded. All witnessed elements of the sperm preparation process should be recorded. As part of their risk assessment for sperm preparation (and only for sperm preparation), the PR and senior embryologist may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it. (CoP guidance 18.30) **Action to be completed by**	Done.	The PR's implementation of this recommendation is noted. No further action required.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	29 December 2011.		
GN 17 Storage of gametes and embryos The centre's 'bring forward' system intended to ensure that both the centre and gamete providers have sufficient notice of the end of the initial one year storage period is not robust. Inconsistencies were noted in sample records seen one example being that information held in the laboratory records regarding the consented storage period for one sample was inconsistent with that documented in the gamete provider's primary medical record on one instance. The centre is at risk of non-compliance with Schedule 3, 8 (1) and (2) of the Act	The centre should review their current practice to ensure that the 'bring forward' system is effective in alerting the centre to contact patients with gametes or embryos in store in sufficient time to make an informed decision regarding the continued storage or otherwise of their stored material. The centre should conduct a comprehensive audit of storage consent records held in the laboratory against the consents recorded in the patient's primary medical record. The findings of the audit and corrective actions required should be documented and submitted to the centre's inspector.	A review, to be followed by an audit is on-going and should be completed by 30 March 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	The centre should also review the bring forward system to identify how the system should be improved to ensure that it is effective in ensuring that all samples are stored in compliance with the gamete provider's consent. A summary of the review and corrective actions implemented should be provided to the centre's inspector. **Action to be completed by 30 March 2012**		
GN 31Record keeping and document control Inconsistencies in record keeping and storage as demonstrated during an audit of records conducted on inspection indicates that the centre does not have robust procedures and processes in place for managing data and	The centre should review their documented procedures for managing data and information to ensure that there is an organised and unified system in operation throughout the centre for the accurate and consistent recording of information and that all patient/donor records required for full traceability	Work is on-going and will be completed by 30 April 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
information in place. (Standard licence conditions T15(a) T33(b) T37, T39(c, e), T46, T47 and T48)	are complete and retained in an accessible form for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority. All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation. The content of these documented procedures should be communicated to all licensed centre staff and the competence to perform them should be assessed and documented.		

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	A summary of actions implemented to ensure that the systems for management of information are robust should be submitted to the HFEA. **Actions to be completed by 30 March 2012**		
GN 30 Confidentiality and privacy Identifying donor information recorded in a donor gamete recipient's medical record is considered to be a risk to maintaining the donor's confidentiality and privacy. This is potentially non-compliant with the requirements of S.33 of the Act	The centre should review their SOP for maintaining confidentiality to ensure that all patient and donor related information is held securely and only disclosed in circumstances permitted in law. The SOP should document the systems in place to prevent the unauthorised disclosure of information while guaranteeing the traceability of gamete, embryo or tissue (cell) donations.	Work is in progress and should be completed by 30 April 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented. The centre should ensure that appropriate quality indicators relevant to the maintenance of confidentiality are established and the procedures for maintaining the confidentiality of donors and the traceability The findings of the audit and corrective actions required should be documented and submitted to the centre's inspector. **Actions to be completed by 30 March 2012**		

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
GN 7 Legal parenthood The centre does not have a written procedure in place to ensure that should a woman being treated vary or withdraw her consent to the nominated second parent, the nominated second parent is informed of this change in writing. (Standard licence condition T65)	A written procedure should be established to ensure that should a woman being treated vary or withdraw her consent to the nominated second parent, the nominated second parent is informed of this change in writing. The content of this SOP should be communicated to all licensed centre staff and the competence to perform this SOP should be assessed and documented. **Action to be completed by 29 December 2011.**	SOP nearing completion which should be achieved by 31st January 2012	The PR requested an extension to this deadline to accommodate key staff leave which was agreed by the executive. The PR has since confirmed that this recommendation has been fully implemented.
GN 26 Equipment and materials The actions to be taken in the	Procedures for the operation of each piece of critical equipment must be established and these procedures must	Action is on-going and should be completed by the due date of 30 March 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
event of a low oxygen alarm sounding are not documented. This issue remains unresolved from the last inspection. (Standard licence condition T27) Validation documents for certain critical temperature sensitive equipment used in the preparation and incubation of gametes and embryos did not include temperature mapping to demonstrate that there are no significant temperature inconsistencies (hot or cold spots) within the piece of equipment indicating that validation has been only partially completed. (Standard licence condition T24)	document the action to be taken in the event of malfunctions or failure. All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical		

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available. The PR should submit an action plan listing the critical equipment that is to be mapped and the anticipated timescale for completion of the validation to the HFEA. **Actions to be completed by 30 March 2012**		
GN 27 Adverse incident reporting The centre's adverse incident protocol does not indicate the reporting requirements of the HFEA for incidents or adverse events, the process to be following to inform the HFEA of	The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a	SOP nearing completion which should be achieved by 31st January 2012	The PR has given assurance that this had been implemented.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
such event or the timescales in which an actual or near miss incident or adverse event is to be reported. (Standard licence condition T118 and T119 and Directions 0011))	licence relates and any relevant third party premises. The procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay: a. all relevant available information about suspected serious adverse events and reactions, and b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions. A copy of the revised procedure to be submitted to the HFEA. **Actions to be completed by 30 March 2012.**		
GN 15 Procuring, processing and transporting of gametes and embryos	The centre should ensure that before the centre distributes gametes and embryos there	Action to be completed by 30 March 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre does not have a procedure in place for the investigation of any recall as an adverse incident. (CoP interpretation on mandatory requirements 15(c) and standard licence condition T118)	are procedures in place that define the responsibilities and actions required when a distribution is recalled and a procedure for investigating the recall as an adverse incident. The centre may wish to consider incorporating this into their incident reporting SOP. **Action to be completed by 30 March 2012**		monitoring process.
The centre has only partially validated their laboratory processes. (Standard licence condition T72)	The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the centre itself, or on data from published studies or from well -established processing procedures, by retrospective evaluation of the clinical results of tissues provided by	This is on-going and will be completed by 30 April 2012	The PR has requested that he deadline for the completion of this work to be extended which the Executive has agreed. This will not be monitored as part of post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	the establishment. The PR should submit an action plan listing the critical processes that require validation and the anticipated timescales for completion of the validation programme to the HFEA. **Actions to be completed by 30 March 2012**		
GN 8 Welfare of the child The centres has not established quality objectives or indicators relative to welfare of the child assessment processes and procedures (standard licence condition T35) nor audit these processes against quality objectives, approved protocols and regulatory requirements within the last two years. (Standard licence condition T36)	Quality objectives or quality indicators relevant to welfare of the child assessment procedures should be established and an audit conducted to assess how far welfare of the child procedures comply with approved protocols, regulatory requirements and quality indicators. The PR should provide evidence to the HFEA of the establishment of these	The clinic conducted an audit on Welfare of the Child assessment in 2011. However a further more detailed audit will be conducted this year and should be completed by 30 June 2012	The PR's commitment to this is noted and will be monitored as part of the post inspection monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	indicators. **Actions to be completed by 30 June 2012.**		
GN 23 Quality Management System - audit Observations and review of audit findings in the course of inspection suggest that the centre's consent and witnessing and other audit procedures were not fully compliant with the requirement of standard licence condition T36.	The PR should review audit processes to ensure that they are effective in monitoring compliance with the regulatory requirements, own protocols and quality indicators as required by standard licence conditions. **Actions to be completed prior to the audits recommended in this report being conducted and no later than 29 December 2011**	The generalisation inplied in this statement is questionable. The clinic has conducted several quality and effective audits over the 9 year period of carrying out licensed procedures. examples include Audit of our complaint procedure, patient satisfaction audit and welfare of the child audit.	The executive acknowledges the work previously done by the centre in conducting audits of a number of areas of practice and does not wish to infer that this activity is without worth. However, the executive is keen to ensure that all audits demonstrate that the procedures and processes are compliant with the centre's SOPs and regulatory requirements. This was not demonstrated in two instances seen on inspection whereby audits had been conducted for witnessing and consent but neither audit picked up that the procedure being followed was partially incorrect. The executive will continue to work with the centre towards achieving compliance. An

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			revised date 30 April 2012 for the implementation of this has been agreed.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting
9 March 2012

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

Minutes – Item 2

Centre 0198 – (St Jude's Clinic for Fertility and Gynaecology) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information(Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that this centre has been licensed since January 2002 and has a satellite agreement with the centre's sister unit, St Jude's Hospital, Newcastle-under-Lyme.

2. The Panel noted that the interim inspection was conducted over two days, one week apart, and that the inspection was continued on a second day because information brought to light during a records audit prompted further exploration of traceability and confidentiality systems and processes.

3. The Panel noted that the centre was last inspected on 13 August 2009 for licence renewal following which a treatment and storage licence was granted for four years without additional conditions.

4. The Panel noted that from April 2010 to March 2011 the data held on the HFEA register for in-vitro fertilisation and intra-cytoplasmic sperm injection (IVF/ICSI) shows the centre's success rates are in line with national averages across all age ranges.

5. The Panel noted that at the time of the inspection there was a number of areas of practice that required improvement, including three critical areas of non-compliance, four major areas of non-compliance and six other areas of non-compliance or areas of poor practice.

6. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that the three critical areas, one major and two other of non-compliance or areas of poor practice have been fully implemented.

7. The Panel noted that the PR has given a commitment to fully implement the three major and five other areas of non-compliance within the agreed timescales, and the positive response from the PR.

8. Notwithstanding the progress since the inspection, the Panel noted the number of serious issues raised, and that some of these issues had been raised on the previous inspection visits.

9. The Panel noted the inspectorate's recommendation to the continuation of the centre's licence without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timeframes.

Decision

10. The Panel noted that the Inspectorate are currently awaiting an audit report due on 30 March 2012.

11. Given the number and seriousness of the issues raised in the report and the fact that several are still outstanding, the Panel agreed to adjourn this item until the Inspectorate have had time to assess the report referred to in paragraph 10 above.

12. The Panel agreed to reconsider this item at the earliest opportunity once the audit report has been assessed by the Inspectorate.

Signed: Peter Thompson Date: 23/3/12.
Peter Thompson (Chair)