Interim Inspection Report

St Jude's Women's Hospital
0198

Date of Inspection: 9th August 2007
Date of Licence Committee: 29th October 2007

CENTRE DETAILS

Centre Address	263 Penn Road, Penn, Wolverhampton West Midlands WV4 5SF
Telephone Number	01902 620 831
Type of Inspection	Interim
Person Responsible	Mr Jude Adeghe
Nominal Licensee	Dr Charman Lal
Licence Number	L0198/6/a
Inspector(s)	Ms Allison Cummings
	Mr Tony Knox
	Ms Sarah Hopper
	Ms Gillian Walsh (observing)
Fee Paid - date	n/a
Licence expiry date	1st October 2010

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About the Inspection:
This inspection visit was carried out on Thursday 9th August 2007 and lasted for 8.5 hours. The report covers the pre-inspection analysis, the visit and information received between July 2006 and August 2007.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the 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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

St. Jude's Women's Hospital is a small stand alone unit in a private house located on the outskirts of Wolverhampton. There is also an annex attached to the centre which the Person Responsible (PR) reported is used as a Doctor's rest room. It has been providing Donor Insemination and In Vitro Fertilisation (IVF) treatments since 2002. It is graded as a small size activity centre and in 2006 approximately 220 treatment cycles were carried out. All patients are private referrals from GP or through self-referral.

With the implementation of the European Union Tissues and Cells Directive (EUTD) in July 2007, the centre is now also licensed for Intra Uterine Insemination (IUI) treatments with patient's own gametes. The PR stated that the centre has been working hard in other areas to comply with the Directive and noted improvements to the centre including International Standards Organisation (ISO) certification, the establishment of an online forum for patients as well as a support group for patients.

The PR has recently informed The Authority of the establishment of a satellite centre located in Newcastle-under-Lyme called Newcastle Gynaecology Services, St Jude's Hospital. A third party agreement between the primary centre and the satellite centre was evidenced on the day of inspection. The PR stated this centre can provide private patients with ovulation induction, pregnancy testing, scanning and counselling services. He also commented that at the premises for this satellite centre had been inspected by the Health Care Commission (HCC) two weeks prior to the HFEA visit.

Activities of the Centre

Licensed treatment cycles	226*	IVF and ICSI (with own gametes or donor eggs/sperm). IUI is now also a licensed treatment cycle although the centre's activities will be reported to the HFEA separately and on an annual basis. The report for this activity is due in December 2007.
Donor Insemination	0*	
Unlicensed treatments	✓	Surrogacy (partial and complete) Egg sharing Altruistic donation Ovulation induction Surgical sperm retrieval and assessment Reversal of sterilisation Tubal and other reproductive surgery Ovarian Diathermy Myomectomy
Storage	✓	Eggs, sperm and embryos.

* HFEA unverified statistics from 1st January 2006 – 31st December 2006

Summary for Licence Committee

As noted in section one, the Person Responsible Entry Programme was due for completion and submission to the HFEA on the 30th April 2007. The Executive had not received the completed workbooks prior to the inspection. A one month time frame was negotiated with the PR on the day of inspection however, these are still outstanding.

The Licence Committee should note that significant improvements are required in all five sections. The Executive recommends that the Licence Committee considers what regulatory action, if any, should be taken.

Risk Assessment

Prior to the inspection, St Jude's Women's Hospital scored an amber risk rating of 26%. Following this inspection, the risk score remains the same.

Upon assessment of the centre's application to vary their licence with the implementation of the EUTD, the centre scored a low risk rating of 7%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvements required	Significant Improvements required
		✓

Evaluations from the inspection

Topic	No Improvements required	Some Improvements required	Significant Improvements required
1. Organisation			✓
2. Quality of the service			✓
3. Premises and Equipment			✓
4. Information			✓
5. Laboratory and clinical processes			✓

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Organisation 1. The HFEA has not received the PR's Entry Programme, the HFEA's PR assessment process outlined in Standard 4.1.5. The deadline for submission was 30th April 2007.	A one month timescale was negotiated with the PR on the day of inspection although this has now passed.	Within 14 days of the licence condition taking effect.
2. The PR has failed to disseminate Alert 23 (witnessing) to the Embryologist. This is a breach of Standard 4.1.7(d) and 4.1.8(c).	The PR should disseminate this alert (and future alerts) to all relevant staff and respond to the recommendations as necessary.	Immediately.
3. Agreements with third parties who supply products or services that have potential to affect the quality and safety of gametes or embryos have not been formalised. This is a breach of Standard 4.2.10.	The PR should ensure that agreements with third parties are formalised and copies of these should be submitted to the HFEA within the set timescale.	1st December 2007.
4. Note breach of Section A.13.3 of the centre's standard licence conditions which states that there is a 28 day limit for the payment of any additional fees to The Authority as defined in Section 16(6) of the 1990 HFE Act.	The PR should ensure that payments are made to the HFEA within the 28 day limit.	Licence condition A.13.3 has now been complied with.
Quality of Service 5. The centre's complaints register did not accurately record all complaints that they had received. This is a breach of Standard 9.2.2.	Records should be kept of all complaints and their investigations, together with the corrective actions.	Immediately.

Premises 6. Note breach of Standard 6.3.4(b) regarding the need for appropriate emergency clinical facilities for the patient recovery rooms.	The PR should ensure that effective nurse call systems are fitted in all patient recovery areas. The frame for the oxygen cylinder should either be repaired or replaced so that it can be transported to the patient recovery rooms quickly in the event of an emergency.	Immediately.
7. The doors to the theatre were seen to be open. As there is a hatch large enough for human access between the theatre and the laboratory, the security of gametes and embryos stored in the laboratory is potentially compromised. This is a breach of Standard 6.3.8.	All staff should ensure that the door to the theatre remains securely closed at all times.	Immediately.
8. Not all equipment and processes that affect the quality of gametes/embryos and safety of patients have been validated. This is a breach of Standard 6.4.2.	The PR should ensure that the validation of equipment is extended to cover the requirements outlined in The Standards.	Within three months of receipt of the licence committee minutes.
Information 9. A large number of pregnancy outcome forms have not been submitted to the HFEA. This is a breach of Direction 2006/6, paragraph 4 (v) that provides timescales for submitting forms to The Authority.	The PR should ensure that all outstanding forms are submitted to the HFEA within the required time frame.	Within one month of receipt of the licence committee minutes.
Clinical and Laboratory Practice 10. One of the ten dewars contained embryos that had expired their statutory storage period of June 2007. This is a breach of section 14(1)(c) of the 1990 HFE Act regarding	The PR has provided written confirmation that these embryos have been allowed to perish. The PR should ensure an effective system is in place to review statutory	Immediately

storage periods for gametes and embryos as well as a breach of section 3(1A)(b)(i) of the 1990 HFE Act which provides that no person shall keep an embryo except for in the pursuance of a licence. A breach of section 3(1A)(b)(i) is an offence under section 41(2)(a) of the 1990 HFE Act.	periods for gametes and embryos.	
11. Not all products that come into contact with gametes and embryos are traceable. Additionally, the centre's traceability protocol did not include all laboratory processes, for example, the freezing and thawing of gametes (as outlined in section 4 of the report: Information). This is a breach of Standard 7.3.1 regarding traceability.	Laboratory procedures and protocols should be extended to include the critical processes identified in The Standards.	Within one month of receipt of the licence committee minutes.

Non-Compliance

Area for improvement	Action required	Time scale
Quality of Service 1. The PR was found to be making inconvenience payments to egg donors. These acts are non-compliant with Chair's Letter (06)01 regarding payments for donation.	The PR should ensure payments made for the donation of eggs and sperm are in accordance with the Sperm, Eggs and Embryo Donation (SEED) review outlined in the Chair's Letter.	Immediately.
Premises 2. One of the ten dewars (the same dewar that contained embryos that were stored beyond their expiry date, as noted in breach 10.) was not connected to a local alarm system and an auto-dialler facility. This is non-	All dewars used for the purpose of storing gametes and embryos should be connected to a local alarm system or an auto-dialler facility in the event of dewar failure.	Within one month of receipt of the licence committee minutes. The embryologist has confirmed that the dewar concerned has been taken out of service.

compliance with Chair's Letter (04)03. <u>Clinical and Laboratory Practice</u> 3. Note non-compliance Code of Practice, 7th edition G.13.2.1 and G.13.1.1(e) regarding witnessing procedures.	The witnessing practice should be reviewed with respect to the witnessing guidance outlined in the Code of Practice, 7th Edition.	Immediately.

Proposed licence variations

The licence committee have proposed to vary the treatment and storage licence by the following condition being added to the licence, namely: *The Person Responsible shall, within 14 days of the date upon which this condition takes effect, submit to the Authority his completed PR Entry Programme (PREP).*

Changes/ improvements since the last inspection on 18th July 2006

Recommendation	Action taken
All storage dewars in use should be fitted with an auto-dialler facility and a local alarm system within one week of the inspection in July 2006, in accordance with CH (04) 03.	On the day of inspection, it was noted that nine of the ten storage dewars are now connected to an auto-dialler facility and local alarm system.
A protocol for response to dewar failure and a spare dewar should be acquired to enable transfer of samples in the event of a vessel failure is required, in accordance with CH (04) 03. The timescale for this was August 2006.	The centre has since acquired an emergency storage vessel and this was noted by the Inspectorate on the day of inspection. A relating protocol was submitted to the Executive following the last inspection.
Oncology samples should be split between storage vessels and a written protocol for this to be submitted to the HFEA within 1 month of the inspection in July 2006, in accordance with CH (04) 03.	On the day of the inspection, the Embryologist stated that all oncology samples had been split between storage vessels. This was also noted on the laboratory audit submitted prior to the inspection.
A laboratory audit of stored material should conducted in accordance with section 9.11 of the Code of Practice, 6th Edition. The findings of this should be submitted to the HFEA by the first week of September 2006.	The audit was carried out between 1st and 19th September 2006. This was submitted to the Executive soon after its completion.
The centre should ensure the Counsellor is fully integrated into the provision of services and that is expected that all professional staff engage actively in Continuous Professional Development (CPD) as provided and recommended by their professional bodies. This in accordance with 1.7 of the Code of Practice, 6th Edition.	The Counsellor interviewed at the time of last inspection has since been replaced. A Counsellor with the appropriate qualifications and CPD was appointed in February 2007.
The centre should version control all clinical, nursing, and scientific protocols in preparation for the implementation of the EUTD. It was agreed with the PR that these will be submitted to the HFEA by 31st July 2006.	The required protocols were submitted to the HFEA within the allocated timeframe.
A system for obtaining patient feedback should be implemented as recommended in section 2.27 of the Code of Practice, 6th Edition.	Evidence of this was seen on the day of inspection, including an audit of all written comments in section 17 of the questionnaire.

Additional licence conditions and actions taken by centre since last inspection

C	None
A	**Complied Y/N**
C	
A	**Complied Y/N**
C	
A	**Complied Y/N**

Report of Inspection findings

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
Since the last inspection, the Inspectorate agreed that the centre has made significant effort to implement a Quality Management System (QMS). This piece of work was sourced by an external company. An organisational chart is in place and this was provided during the inspection. Staff interviewed during the inspection were aware of the reporting pathways for complaints and incidents. The PR visits the new satellite centre in Newcastle-under-Lyme on a weekly basis as he undertakes work there in a day case surgery. He showed an understanding of the importance and procedure for submitting Intention to Treat forms to the HFEA as required by Direction 2007/1 and has implemented a system to ensure these are reported.
Areas for improvement
The Person Responsible Entry Programme, a study package to ensure suitability of the PR was due for submission to the HFEA on the 30th April 2007. This is still outstanding and the PR should ensure this is completed and submitted to the HFEA within one month of the day of inspection, as negotiated with the PR. The Embryologist stated she had not been informed of the most recent HFEA alert 23 on witnessing. The PR should ensure that alerts are disseminated to all staff and responded to as necessary. Third party agreements were reviewed against the list of those submitted as part of the PR's EUTD application in March 2007. Although some of these were seen to be formalised, agreements with third parties who supply products that have the potential to affect the quality and safety of gametes or embryos were not seen to be in place. As this is now a requirement, the PR should ensure these have been formalised as soon as possible.

Payments to the HFEA take an average of 108 days. The outstanding balance was received by the HFEA the day before the inspection. When this was discussed with the PR, he explained that large outlays of money had been made to improve the laboratory and to implement a QMS so that that centre could achieve compliance with the requirements of the EUTD. The PR stated he anticipates more regular payments to the HFEA in the future. The PR should ensure that payments are made within the 28 day limit set by the HFEA.
Executive recommendations for Licence Committee
Note breach of Standard 4.1.5 regarding HFEA's PR assessment process. Note breach of Standard 4.1.7(d) and 4.1.8(c) regarding the PR's responsibility to disseminate information to centre personnel. Note breach of Standard 4.2.10 regarding third party agreements. Note breach of section A.13.3 of the centre's standard licence conditions which states that there is a 28 day limit for the payment of any additional fees to The Authority as defined in Section 16(6) of the 1990 HFE Act.
Areas not covered on this inspection
Risk management, contingency arrangements and clinical governance.

Evaluation
Significant improvements required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

Success rates for the period of January to December 2005 were in line with the national averages. Based on the clinical pregnancy rates for the period of January to December 2006, overall live birth rates for that period should be favourable or in line with national averages. Please refer to the table below:

	IVF	FET after IVF	ICSI	FET after ICSI
Clinical pregnancy rate per treatment cycle: 01/01/06-31/12/06	38.18%	23.40%	27.66%	13.79%
Live birth rate per treatment cycle: 01/01/05-31/12/05	27.78%	11.54%	18.33%	5.26%

According to HFEA statistics, in the period January to December 2006 there were no donor insemination cycles performed. There was only one live birth event which resulted in a multiple birth.

HFEA verified data from March 2002 to April 2005 indicated that:

- IVF/ICSI success rates for age band 38-39 years were significantly lower than the national average.
- FET success rates for age band 38-39 years were significantly lower than the national average.

All other age groups for both IVF/ICSI and FET cycles were in line with national averages.

Areas of firm compliance

Patient records were seen to be kept securely in key-locked filing cabinets in a room adjoining a lower ground consulting room. The windows in the room are secured with metal bars.

A complaint handling procedure for patients was seen in the waiting area and appeared to be fit for purpose.

A patient satisfaction survey has been implemented since the last inspection and the audit results of these were reviewed by the Inspectorate. No issues of concern were highlighted in any of the returned forms.

The Counsellor was interviewed by the Inspectorate was found to be appropriately qualified. She was appointed on a sessional basis by the PR in February 2007, initially for a trial period of six months. The Inspectorate noted that the continuation of this arrangement is pending a review by both parties. Patients are entitled to three free counselling sessions per treatment and appointments take place in one of the consulting rooms on the premises. The Counsellor stated she has no set days although she is committed to Birmingham Women's Hospital every Tuesday and Wednesday. An audit of the counselling service was provided by the PR prior to the inspection. It concluded that from January to June 2007, 16 patients (including donors) accessed the counselling service. This is an uptake rate of 22%.

Areas for improvement

The Inspectorate also found that the only complaint registered did not contain the corrective action. Records should be kept of all complaints and their investigation, together with the corrective action.

As evidenced from written patient information and interview with key staff, the counselling service can only be accessed through request from the clinical team. Patients should be able to access the counselling service independently of the centre where treatment is being sought.

The Inspectorate also noted that the Counsellor is not involved in the multi-disciplinary team meetings however, she stated she is updated informally by the PR when she visits the centre. The PR should ensure the Counsellor is informed of centre updates and has opportunity for making suggestions. Records of meetings should be kept and made available to the Counsellor.

As egg donors are actively recruited, the Inspectorate asked to see evidence of any payments made. It was noted that donors are made 'inconvenience payments' in addition to other out-of-pocket expenses. The PR should ensure payments made for donation are in accordance with the Sperm, Eggs and Embryo Donation (SEED) review in CH (06) 01.

Executive recommendations for Licence Committee

Note breach of Standard 9.2.2 regarding complaint handling.
Note non-compliance of CH (06) 01 regarding payments for donation.

Areas not covered on this inspection

Protection of children arrangements (for patients under 18yrs).

Evaluation

Significant improvements required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
Recent improvements to the laboratory were noted by the Inspectorate. The Embryologist stated the laboratory air quality was checked in March 2007 and found to be of the standard expected by the EUTD. She also explained that the company who have been contracted to change the air filters will also be monitoring the air quality, both background air quality in the laboratory/theatre and air quality in the flow hoods. It is planned that they will visit the unit and conduct these tests every four months. Records were not checked on the day of inspection. Other areas of firm compliance noted by the Inspectorate in the laboratory included evidence of equipment monitoring and Portable Appliance Testing (PAT) of key pieces of equipment. Two low oxygen monitors are in place with calibration logs. A spare dewar was seen to be available for any emergencies.
Areas for improvement
The Inspectorate observed that the male production room and one of the two recovery rooms did not contain a nurse call system. The second recovery room contained two single beds and an operating nurse call system although patients would need to reach behind the bed to access the wall-mounted system. The Inspectorate recommended that the recovery area with a single bed and the producing room should have some form of audible alarm put into them to ensure that the patients can call for assistance if required. The recovery rooms contained no other emergency equipment although in response to this, the PR stated an oxygen cylinder and the emergency trolley would be wheeled into the recovery room. However, when the Inspectorate examined the oxygen cylinder closely, it was found that the frame enabling it to be wheeled to the recovery room had a broken leg, meaning that it would need to be lifted. This would be extremely heavy, considering its size. The PR stated that the frame for the oxygen cylinder would be repaired and that an oxygen cylinder would be acquired for each patient recovery room. The oxygen mask and tubing attached to the cylinder was found lying on the floor of theatre by the Inspectorate. The Inspectorate noted that during the inspection the doors to the theatre were seen to be open. This caused some concern to the Inspectorate as the hatch between the theatre and the laboratory was seen to be big enough for human access therefore potentially compromising the security of the gametes and embryos stored within it. The Inspectorate found the usual access to the laboratory secure by means of a key-pad locked door. The PR should ensure that the security of the laboratory is maintained at all times.

Within the theatre, a trolley contained an unsecured container of medications used for anaesthesia. It was confirmed by the PR that there is no written record of medication counts and expiry dates. When the Inspectorate interviewed the Nurse Manager, she stated that she would look into a way of improving the checking of the drugs on the trolley.

The landing outside of the theatre and the laboratory was seen to be used as a nurse's station and also to store gas cylinders. The chains for re-enforcing the safety of the cylinders were not secured to the wall and therefore this arrangement was ineffective. It was recommended that more effective means of securing the cylinders to the wall is implemented. This was agreed by the PR.

The Inspectorate noted that one of the ten storage dewars was not connected to an alarm system or an auto-dialler facility. The Embryologist explained this was because the dewar contained embryos that were due for perishing as they had reached the expiry of the statutory storage period (see section 5).

A logging system has been fitted to the nine of the dewars and the two incubators. This system records the level of nitrogen and vapour in the tanks and the carbon dioxide, temperature and humidity in the incubators. If any major deviations are sensed then it alarms and acts as an auto dialler system. The Embryologist said she checks the readings each morning but is not currently recording these. The Inspectorate was informed that in the future, this system will be linked to a computer which will produce readouts. Until this is implemented, the Inspectorate recommend that a log is kept to record the readings.

The Embryologist has validated some pieces of equipment such as IVF plasticware. However, it was found that not all equipment and processes that affect the quality of gametes/embryos and safety of patients have been validated. This should be extended to cover all equipment and all processes that occur and affect the quality of gametes/embryos and safety of patients.

Executive recommendations for Licence Committee

Note breach of Standard 6.3.4(b) regarding the need for appropriate emergency clinical facilities.
Note breach of Standard 6.3.8 regarding controlled access to ensure the security of gametes and embryos.
Note Non-compliance of Chair's Letter (04)03 outlining the expectation that all centres storing patients' gametes and embryos to have effective alarms and monitoring systems in place to ensure the safety of cryopreserved gametes and embryos.
Note breach of Standard 6.4.2 regarding validation of critical equipment.

Areas not covered on this inspection

None.

Evaluation

Significant improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Ten patient records were selected by the Inspectorate during the inspection and reviewed for completeness. Of these, four had discrepancies: 1) One set of patient records did not account for the 'Welfare of the Child'. The Nurse Manager stated this was difficult to determine as the patient came from abroad for treatment and it was difficult to make correspondence with the relevant people. 2) A HFEA Male Treatment (MT) form was not completed accurately in one patient record. 3) In one set of patient records, the Doctor had not countersigned that he had witnessed the completion of a consent to egg share. However, this was completed in other records as per the centre's procedure. 4) One set of patient records had a conflicting section on the HFEA form re length of storage of embryos. This form was actually originally completed at another centre where embryos were created before transfer to St Jude' Women's Hospital. Five sets of records were audited for evidence of witnessing in the laboratory. Some issues noted and these are discussed in section 5.
Areas of firm compliance
During a patient interview, the Inspectorate noted satisfaction with the information they had received about their treatment. They stated it was in a format that was written clearly and therefore easy to understand. The Inspectorate was informed that the patient felt she could approach centre staff at any time and that prompt replies were provided for requests for treatment information. The PR added that treatment information could be found on the centre's own website. A review of the centre's website by the Inspectorate concluded that detailed treatment information is available. A sample of documentation reviewed on the day of inspection was seen to be document controlled.
Areas for improvement
The Inspectorate noted that the PR had progressed with the implementation of a QMS since the centre applied to vary their licence in March 2007. Evidence seen on the day of inspection included a quality manual that is almost near completion. The records control and data management protocol were not available on the day of the inspection, however the PR has subsequently supplied their 'Data, Information & Confidentiality' policy. This policy has been reviewed by the Executive and it is recommended that it is amended to incorporate the

requirements on the control of records set out in Standards 5.2.7 and 5.2.8. It should also be drafted to incorporate the confidentiality requirements outlined in Section 33 of the 1990 HFE Act and in the Code of Practice, 7th Edition (see Standard 7.2 and Guidance 10.1 to 10.8).

Prior to the inspection, the HFEA registry department expressed concern over the lack of pregnancy outcome forms submitted with each treatment cycle reported. This was discussed with the PR and Nurse Manager and whilst this issue was acknowledged, the Nurse Manager (also responsible for returning forms to the HFEA) stated recent problems uploading forms using the Electronic Database Interchange (EDI). The Nurse Manager reported rectifying these problems with the assistance of the HFEA technical support team.

A number of laboratory related protocols were reviewed on the day of inspection:

- A traceability protocol has been developed by the Embryologist and this system was reviewed by the Scientific Inspector on the day of inspection. This currently does not include all laboratory processes, for example, the freezing and thawing of gametes.
- It is recommended that a protocol for response to auto-dialler call outs is produced so that staff other than the Embryologist (who is the 4th person on the list) know what to do if faced with an emergency after responding to the auto dialler.
- According to the centre's protocol men producing samples for treatment/freezing should sign the lab sheet to confirm that the name label on the pot, and therefore the sample, belongs to them. This is not occurring always in practice apparently (according to the Embryologist) and this section of the form was seen to be incomplete in all relevant patient files that were checked.
- The centre's witnessing protocol should be updated (see section 5).

Overall, the records were found to be in a disorganised state and it was difficult to find the information the Inspectorate required.

Executive recommendations for Licence Committee
Note breach of Direction 2006/6, paragraph 4 (v) on timescales for submitting pregnancy outcome records to The Authority. Note breach of Standard 7.3.1 regarding documented procedures for traceability of gametes and embryos.

Areas not covered on this inspection
None.

Evaluation
Significant improvements required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	2 (and 1 Nursing Auxiliary)
HPC registered scientists	1
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	1

Summary of laboratory audit
A laboratory audit report on stored embryos and gametes was provided prior to the inspection. The audit was carried out by the Embryologist between 1st and 19th September 2006. It recorded that all oncology samples have been split between tanks as requested by the Licence Committee following the last inspection. The report also highlighted that one set of embryos in storage had an expiry date of June 2007. This was followed up on the day of inspection and the Embryologist confirmed these embryos were still in storage, past their statutory storage period, as she had been trying to contact the couple to see whether they would like to extend the storage period. The Embryologist was reminded that embryos should be discarded once they reach this date as there is a legal requirement for this. Since the inspection, the PR has provided written confirmation that these embryos have been allowed to perish.
Summary of spot check of stored material
No major discrepancies were noted during the Inspectorate's spot check of stored material. One patient's embryos were tracked from paperwork to tank and another set from tank to paperwork. The same process was followed for sperm samples. When tracking a sample from tank to dewar, it was noted that one record of the freeze (two paper records and a computer record are maintained) had not been updated to show a recent change in location within the dewar. The Embryologist should ensure that all records of freezes are updated in response to any changes.

Areas of firm compliance

The Embryologist stated that oncology samples have now been split between dewars as required following last inspection. This process is reflected in laboratory protocols, as noted by the Inspectorate.

It was found that all staff are trained to witness the required steps performed by the Embryologist. She confirmed this during the inspection, stating that she has trained each staff member on the purpose and practice of witnessing. Evidence of this training was not seen on the day of inspection.

It was assessed that there was a sufficient number of suitably qualified members of staff working within the centre. Training plans for 2006/07 were outlined for each staff member except for the current Counsellor. A training folder provided to the Inspectorate for the Nurse Manager contained evidence of CPD training attended.

Areas for improvement

The centre's witnessing practice was reviewed in detail. It should be tightened to meet the requirements:

- Times of witnessing were not recorded although there is an allocated space for this on the witnessing sheet.
- Some of the witnessing steps were omitted. It was noted that:
  1. Witnessing at embryo transfer i.e. movement of embryos from the culture dish to the transfer dish was not recorded.
  2. The dish should be witnessed and recorded again at the time of embryo transfer.
  3. The processes involved in an ICSI procedure require that eggs are moved five times to different dishes. However, none of these steps were witnessed and recorded.

The witnessing laboratory sheet and protocol should be updated to reflect these changes. These changes should be communicated with all staff involved in the witnessing practice.

The Embryologist commented that inter-lab comparisons are currently not conducted. However, they are planning to enrol in UK National External Quality Assessment Service (NEQAS).

The Embryologist records batch numbers and lot numbers of media and some culture dishes. This should be extended so that traceability includes all products that come into contact with gametes and embryos such as dishes and freezing containers.

Executive recommendations for Licence Committee

Note breach of section 14(1)(c) of the 1990 HFE Act regarding storage. This is also a breach of section 3(1A)(b)(i) of the 1990 HFE Act which provides that no person shall keep an embryo except for in the pursuance of a licence. A breach of section 3(1A)(b)(i) is an offence under section 41(2)(a) of the 1990 HFE Act.
Note non-compliance Code of Practice, 7th edition G.13.2.1 and G.13.1.1(e) regarding witnessing procedures.
Note breach of Standard 7.3.1 regarding traceability.

Areas not covered on this inspection
Assessment of patients and donors; safe handling systems; PGD/ PGS.

Evaluation
Some improvement needed.

Report compiled by:

Name	Allison Cummings
Designation	Inspector
Date	7 September 2007

Appendix A: Centre Staff interviewed

The PR, Mr Jude Adeghe and three staff members.

Appendix B: Licence history for previous 3 years

2007

14th May 2007: Variation of Licence under the EUTD Legislation

The Committee agreed to vary the licence to incorporate the requirements of the EUTD.

2006

11th October 2006: Consideration of renewal inspection report

The Committee agreed to renew the centre's licence for a period of three years, with no additional conditions.

9th March 2006: Consideration of an interim inspection report

The Executive presented papers to the Committee that contained the reports of an unannounced inspection, an interim inspection and the report of an interview with the Person Responsible. The Committee decided that the centre's licence should continue with no additional conditions.

2005

10th March 2005: Consideration of interim inspection report

The Committee decided to vary the centre's license to add a condition requesting the Person Responsible demonstrate to the Executive at an interview that sufficient mentoring, education and training to have substantially improved his understanding of the duties of a Person Responsible.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0198

Name of PR Mr Jude Adeghe

Date of Inspection 9th August 2007

Date of Response……

Please state any actions you have taken or are planning to take following the inspection with time scales

ACTIONS TAKEN SO FAR

1) The PR entry programme is nearing completion and will be with you the end of the month

2) Counselling:
What was previously a six month working arrangement with our independent counsellor has now been formalised and extended on one year rolling contract basis. A new counselling room has been agreed. The counsellor is also agreeable to direct access / contact from patients. Forward dates for team meetings will be circulated to the counsellor and she will endeavour to attend as much as possible

3) The actions taken so far regarding laboratory / embryology matters are detailed in the comments by the senior embryologist which you should received by now (SEE BELOW)

4) The last outstanding payment to the HFEA was put in the post two days ago, bringing fully up-to-date

Embryology Comments Relating to HFEA Interim Inspection Report
St. Jude's women's Hospital 0198.
Date of Inspection: 9th August 2007

Reference to S6.4.2 Management of equipment and materials

- All new equipment has been validated with certificates.
- Maintenance for other equipment will be maintained annually and the Companies will be asked to provide test results. See maintenance book for records
- Cleaning and sterilization of equipment is recorded in the Embryology equipment-cleaning book.

Reference to S.4.2.10 Establishment and review of contracts with third parties

- There are Third party agreements with some companies relating to gametes and embryos. This will be completed

Reference S.7.3 Traceability and coding

- Comprehensive protocols for freezing and thawing are in place either in the Laboratory protocols or the QC/QA manual.
- A record of all freezing plasticware will also be recorded. Medium has been included in the QC/QA manual.

Reference G13.1.2 witnessing Clinical and laboratory procedures

- Witnessing form now broken down in more detail to cover points raised. However I must state that at each stage of movement of embryos /gametes it has been witnessed by a member of staff. Even though it may not have been broken down into those particular sections.
- Protocol for training witnessing is now being completed.
- All men are now signing Work Sheet declaring that the sample produced is their sample.

Other Comments from HFEA

- Un-alarmed Dewar is now out of service; therefore all other Dewars are alarmed, attached to an alarm system with a dial out service.
- The protocol has been extended to include the response to auto-dialler call out for all other staff if faced with an emergency.
- Alert number 23. I informed the inspector that I could not remember if I had seen this alert but showed her my file of alerts that had been forwarded to me. As a general rule all alerts are passed onto me and maybe this one alert had not arrived or was in the process of being handed over to me.
- Safety of CO2 Cylinders has always been a priority and is always chained to the wall, this has been passed in safety checks. There is now a bar cage surrounding the CO2 cylinders as well as being chained to the wall as an extra safety measure.
- The log for the low and high level temperature in the cryo-refrigerators and the temperature, humidity and CO2 levels will be logged onto the computer by the 12 th October. At the moment it is being logged by hand.
- The occasional embryo/gamete sample has changed position temporarily due to the fact that the alarms were being fitted into the cryo-refrigerators and this had been recorded in the freezing register, but not on the freezing sheet. I did not think it necessary if they were going back into their original position to change all paper work. * **The Embryo / Gamete audit is underway and all paper work will be amended to the audit***

Comments from Senior Embryologist

I think it is very sad that the inspection team feel that significant improvements are required in the Laboratory and indeed in all areas of their inspection. Fundamentally most of the requirements for the Embryology Laboratory have now been addressed and those outstanding will be dealt with as soon as possible.

We are a very hard working team and we make every effort to comply with all regulations that are bestowed upon us and indeed have made many significant changes that seem to have been ignored by the HFEA inspection team.

I had a lot of positive comments from the Inspector and how pleased she was to see the effort and changes that had been made to the Embryology Laboratory. No one minds constructive criticism if it helps to improve the quality of the laboratory, but the feeling when you read the Inspection Report is one of being hung out to dry.

Every effort will be made to ensure the compliance of all statements made in the Inspection Report and hope that the HFEA Inspectors will continue with useful constructive comments.

Signed _____ Senior Embryologist

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

COMMENTS BY PERSON RESPONSIBLE – MR J ADEGHE
Re: HFEA DRAFT INSPECTION REPORT (Inspection on 9th August 2007)

General Comments:
The report is unjustifiably harsh and at significant variance to the positive verbal feedback we were given on the day of the inspection. You should by now have received the comments by the clinic's senior embryologist which concurs with this view.

Illustration: Following the HFEA inspection in July 2006 the evaluation was
"Some Improvement required" for:

- INFORMATION
- LABORATORY AND CLINICAL PROCESSES

Between that inspection and the recent inspection we have achieved the following:

1. **Gained ISO 9001:2000 accreditation**
2. **Complied with the issues raised in the 2006 inspection report**
3. **Produced an excellent Quality Manual**
4. **Aligned our laboratory and processes with EUTD requirements**

Yet according to this latest inspection report we are now worse off than 12 months ago!!

Conflict of Interest regarding members of the Inspection Panel: We feel it is good practise for members of the inspection team to declare possible conflict of interest before the inspection begins, but this was **not** done on the 9th August 2007.

Specific points:

A) **Dissemination of Alerts to staff**:
The inspection report should have stated that the embryologist had shown them a folder of previous alerts. The slight delay in downloading Alert 23 was because our broadband internet was down at the time. Maybe the HFEA should send paper copies of alerts as well as electronic

B) Complaints Register

We disagree with the suggestion that the complaints register is not up-to-date. The situation that the report is referring to is where the clinic declined to treat a patient because of very poor clinic attendance and aggressive and abusive behaviour towards clinic staff. The patient complained to the HFEA and the GMC but did not actually send us a copy of her complaints. Well, if the clinic does not receive a formal complaint it cannot record it. It is of note here that the HFEA did not notify the clinic about this complaint until the day of inspection.
Less than three complaints in 5 years is not a bad record.

C) Emergency facilities

Of course we have adequate and up-to-date facilities. Our emergency facilities have been inspected by no less than 4 different teams of inspectors in the past and all have found them adequate. Two members of the inspection team on the 9th
August were in disagreement on where the resuscitation trolley should be sited. The trolley for the oxygen cylinder had been sent for repairs at the time of the inspection but it has now been mended. The two recovery rooms as well as the semen production room have a nurse call system.

D) Security

The theatre door (and the hatch between the operating room and the laboratory) was open only **because the inspection was on-going (obviously) !**
Our premises is extremely secure and again previous inspection teams have been well impressed with the different layers of security:

- All windows and possible inlets are protected with security grills
- The whole building is alarmed
- The laboratory and operating room are on the first floor. At the top of the landing is a secure door with a coded lock before you even reach the operating room door which also has a coded lock.
- All doors are always locked except at times when there is on-going activity as during HFEA inspections!

E) Payment to Egg donors

We paid two egg donors £200 (two hundred pounds each). We are being victims of our honesty. We could have called this child care allowance or something more acceptable. The report says payments where made to the donors without stating the actual sum. We feel the actual sum paid should be included in the report in order to put things in proper perspective.

F) Treatment Success Rates

Inexplicably the report refers to live birth rate for a very narrow age band of 38-39yrs for the period March 2002 to April 2005. In our opinion this is inappropriate for the following reasons:

- It is based on very small numbers, so small that you cannot quote a percentage
- If you are going to comment on results for the time frame (2002 -2005), then do so for all age groups together with the actual numbers so people can make a reliable judgement. Otherwise it can be misleading.
- In order to present a balanced and fair report you may want to remark that **our IVF success rate for 2006 (which is more recent and more relevant) is better than**

national average

ACTIONS TAKEN SO FAR

5) The PR entry programme is nearing completion and will be with you the end of the month

6) Counselling:
What was previously a six month working arrangement with our independent counsellor has now been formalised and extended on one year rolling contract basis. A new counselling room has been agreed. The counsellor is also agreeable to direct access / contact from patients. Forward dates for team meetings will be circulated to the counsellor and she will endeavour to attend as much as possible

7) The actions taken so far regarding laboratory / embryology matters are detailed in the comments by the senior embryologist which you should received by now.

8) The last outstanding payment to the HFEA was put in the post two days ago, bringing fully up-to-date

SIGNED: Mr J. Adeghe PhD, FRCOG, MIHM.

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

29 October 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

St Jude's Women's Hospital (0198)
Interim Inspection

Members of the Committee:	In Attendance:
Jennifer Hunt, Lay Member – Chair	Trish Davies, Director of Regulation /
David Archard, Lay Member	Deputy Chief Executive
Sally Cheshire, Lay Member	David Gomez, Legal Adviser
Neva Haites, Professor of Medical	Stephanie Sullivan, Head of Inspection
Genetics, University of Aberdeen,	Gill Walsh, Inspector
present via conference telephone	Claudia Lally, Committee Secretary
	Providing Legal Advice:
	Heledd Lloyd-Jones, Morgan Cole
	Solicitors

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

The following papers were considered by the Committee:

- papers for Licence Committee (41 pages)
- 4 papers were tabled:
  - Updated risk assessment
  - Licence Committee minutes from 10 March 2005, 22 June 2005 and 9 March 2006.

1. The papers for this item were presented by Allison Cummings, HFEA Inspector. Ms Cummings informed the Committee that this centre has an updated risk score of 32%, in the medium range. Ms Cummings informed the Committee that a number of breaches of the Act and of the Code of Practice had been identified at the inspection visit and significant improvements were required under all five topics inspected. Ms Cummings drew the Committee's attention to the responses by the Person Responsible and by the Senior Embryologist to the inspection report. The Committee asked Ms Cummings to discuss the breaches in turn and to draw their attention to the response from the Person Responsible or Senior Embryologist to each point.

2. The Committee considered the finding in the report that the Person Responsible had failed to disseminate Alert 23 to the Embryologist, in breach of Standards 4.1.7(d) and 4.1.8(c). The Committee noted the response by the Person Responsible that the delay was related to problems with the centre's internet connection and his suggestion that a hard copy of Alerts should be sent to centres. The Executive informed the Committee that Alerts are sent to centres in both electronic and hard copy format. The Committee decided to remind the Person Responsible that he is expected to disseminate all HFEA Alerts to the relevant staff in line with the requirements of the Code of Practice.

3. The Committee noted that the Person Responsible has failed to draw up formal agreements with third parties in line with licence condition A.5.1. The Committee noted that the Person Responsible has begun this procedure by drawing up a list of third parties with whom agreements need to be formalised. The Committee requested that this recommendation be fully complied with by 1 December 2007.

4. The Committee noted a finding by the inspection team that the centre had been in breach of standard licence condition A.13.3 by taking over 28 days to pay additional fees to the Authority. Ms Cummings informed the Committee that the centre is currently up to date with its fees and this was noted by the Committee.

5. The Committee noted the finding in the inspection report that the centre's complaints register did not accurately record all complaints, in breach of Standard 9.2.2. The Committee considered the Person Responsible's response to this point and his comment about a particular patient complaint mentioned in the inspection report. Ms Cummings informed the Committee that the report would be amended in response to this comment. Ms Cummings went on to say that irrespective of this particular complaint the complaints register at the centre was seen to be incomplete. The Committee agreed that the Person Responsible must ensure that a record of all complaints is kept as required by Standard 9.2.2

6. The Committee considered the finding in the inspection report that patient recovery rooms required improvement and that the frame for the oxygen cylinder required repair. The Committee considered the response by the centre stating that the oxygen cylinder frame had now been repaired and that both patient recovery areas had nurse call systems. Ms Cummings directed the Committee to the statement in the report that a nurse call system was seen in one recovery room only and that the position of the wall mounted nurse call points would make them difficult to access for a patient recovering in bed. She informed the Committee that she remained concerned that the nurse call systems may not be effective. The Committee decided to remind the centre of its obligation to ensure the effectiveness of these systems.

7. The Committee noted the finding that the theatre doors had been left open in breach of Standard 6.3.8. The Committee noted the response on this issue by the Person Responsible but reminded the centre that the laboratory and the samples stored there should be secure at all times.

8. The Committee noted the breach of Standard 6.4.2 due to the fact that equipment and processes relating to quality and safety had not been validated. The Committee required that this be done within three months of receipt of these minutes.

9. The Committee noted that a large number of pregnancy outcome forms had not been submitted to the HFEA, in breach of Direction 2006/6 and in breach of the statutory licence condition imposed by section 12(g) of the Human Fertilisation and Embryology Act 1990 which requires all licensed centres to provide the Authority with information specified in Directions. Ms Cummings drew attention to the statement by the Person Responsible that this delay was caused by problems with EDI which have now been resolved. This was noted by the Committee.

10. The Committee noted the finding of the inspection report that an embryo had been kept beyond the expiry of its statutory storage period. The Committee noted that this was a breach of section 14(1)(c) of the Human Fertilisation and Embryology Act 1990 and a criminal offence. Ms Cummings informed the Committee that the Person Responsible had reported that the embryo had now been allowed to perish.

11. The Committee noted that the centre's protocols for traceability did not include all laboratory processes and that this is a breach of Standard 7.3.1. The Committee agreed that this should be addressed by the centre within one month of receipt of these minutes.

12. The Committee discussed the finding of the inspection report that inconvenience payments are being paid to egg donors contrary to Direction 2006/1 and the requirements of Chair's Letter (06)01 and in breach of the statutory condition imposed by section 12(e) of the Human Fertilisation and Embryology Act 1990 which prohibits the making of payments not authorised by Directions. The Committee agreed that the Person Responsible should ensure compliance with Directions in relation to the payment of donors.

13. The Committee noted that one of the dewars was not connected to a low-nitrogen alarm with an auto-dial facility. The Committee noted that this was a breach of Chair's letter CH(04)03. They further noted that the dewar concerned has now been taken out of service. The Committee agreed to remind the centre of the importance of compliance with Chair's letter CH(04)03 at all times.

14. The Committee considered the centre's non-compliance with witnessing Directions D2004/4. The Committee agreed that this should be addressed by the centre immediately.

15. Finally the Committee considered the failure by the Person Responsible to submit a Person Responsible Entry Programme (PREP) assessment. The Committee agreed that the number and nature of breaches identified in the inspection report appeared to raise questions about the Person Responsible's understanding of his role, making it particularly important that he attend to this requirement. The Committee noted that at the time of the inspection visit the Person Responsible had agreed a time scale of one month for completing the assessment and that since that time he had agreed that he would submit it by the end of October. The Committee considered whether they could make a condition of the centre's licence that this assessment be submitted and asked for legal advice.

16. The legal advice given to the Committee was that a Licence Committee may vary a centre's licence by the imposition of conditions on notice in circumstances where the Committee has powers to revoke the Licence under section 18(1) of the Human Fertility and Embryology Act 1990 (HFEA1990). The committee was then advised that section 18(1)(c) of the Act provides that a Licence Committee may revoke a licence if it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17 or has failed to comply with directions given in connection with any licence. The Committee was further advised as to the duties of the Person Responsible under section 17, particularly the duty under section 17(1)(c) to ensure that proper arrangements are made for the keeping of gametes and embryos and for their disposal, the duty under section 17(1)(d) to ensure that suitable practices are used in the course of activities, and the duty under section 17(1)(e) to ensure that licence conditions are complied with. The Committee was advised that prior to the imposition of any condition, the Committee was required to give notice of the proposed variation to the Person Responsible and that any condition could not become effective until representations from the Person Responsible had been heard or until the time for making such representations had passed.

17. The Committee agreed that the breaches identified in the report and the large number of significant improvements required called into question the suitability of the Person Responsible. On these grounds they agreed to send notice to the centre of their intention to vary the licence by the addition of a condition requiring the Personal Responsible to submit his completed PR Entry Programme (PREP) to the Authority, within 14 days of the date upon which the condition takes effect.

Signed……. … Date……..
Jennifer Hunt (Chair)