Interim Inspection Report

Assisted Conception Unit,
Guy's & St Thomas' Hospital NHS Trust
0102

Date of Inspection: 5 December 2006
Date of Licence Committee: 14 February 2007

TRIM: 06/3141

Centre Details

Centre Address	4th Floor, Thomas Guy House Guy's Hospital, St Thomas Street London, SE1 9RT
Telephone Number	0207 188 2300
Type of Inspection	Interim
Person Responsible	Yakoub Khalaf
Nominal Licensee	Ian Abbs
Licence Number	L0102/11/e
Inspector(s)	Debra Bloor, Will Lenton (HFEA observer) Helen Kendrew David Gibbon
Licence expiry date	30 June 2008

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About the Inspection

The focus of this interim inspection will be drawn from issues arising from the last inspection or information received. 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, sixth edition Code of Practice, and also to advise centres to work towards compliance with the EU Tissue and Cells Directive 2004/23/EC where relevant.

The report is used to summarise 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 continuation of the centre's licence. The report is also available to patients and the public following the Licence Committee meeting.

Inspection teams are drawn from a team of in-house inspectors and generally comprise a scientist, a clinician or nurse and a generalist. Prior to the inspection, the Person Responsible (PR) completes a pre-inspection questionnaire to provide the HFEA with details of any changes since the last inspection and factual information. Patient questionnaires are sent to the centre for distribution to patients so they can tell directly how good they consider the service is. There is also a self-assessment document for the PR to complete so that they and their staff may identify areas needing improvement. Persons Responsible are required to send the HFEA information on all treatments carried out and this information is gathered through an electronic system. All this information is analysed by the lead inspector prior to the visit taking place.

At the visit the inspection team will assess 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.

Evaluations are given to each topic and 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 PRs 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.
There will be an overall judgement made at the end of the five sections.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received.

This inspection visit was carried out on 5 December and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received in the time period between December 2005 and December 2006. Analysis of HFEA-held register data for the time period from 31 March 2002 to 1st April 2005 and non validated outcome data for the period from 1 August 2005 to 31 July 2006 is included.

Brief Description of the Centre

The centre is part of Guys & St Thomas' Hospitals NHS Foundation Trust and provides licensed treatments to NHS funded and self funded patients from London and the surrounding area. The unit has an active research programme and provides an extensive pre-implantation diagnosis (PGD service).

Activities of the centre for the time period from August 2005 to July 2006[1]

Licensed treatment cycles	1057
Donor insemination	19
Non licensed treatments	Intrauterine insemination (IUI) Ovulation induction Surrogacy
Research	✓
Storage	✓

Summary for Licence Committee

The Assisted Conception Unit of the Guys & St Thomas' Hospitals NHS Foundation Trust is a large unit providing more than 1000 licensed treatment cycles per year. The centre also has an active research programme and provides an extensive PGD service.

The unit has appropriate premises, suitably qualified and experienced staff and adopts appropriate clinical and laboratory procedures. Patients report satisfaction with the facilities and with the treatment that they receive. The centre has been responsive to recommendations made in the previous report and has been proactive in the development of a quality management system and clinical governance strategies.

A number of minor improvements should be considered relating to the following aspects of the centre's practice:

- provision of written information to patients donating or receiving treatment with donated gametes:
- documentation of training;
- induction and training of members of the administration team.

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

[1] Non verified information extracted from the HFEA register which may be subject to change.

Risk Assessment

Risk status 5% - low

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement 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

None observed

Non-Compliance

Area for improvement	Action required	Time scale
The information for patients receiving treatment with donor gametes or donating gametes should be reviewed to ensure full compliance with the requirements of the 6th Code of Practice and relevant Chair's letters.	Information should be reviewed	Information for patients undergoing DI should be revised within 3 months. Information for egg donors/recipients should be reviewed before further treatment is provided.

Recommendations	Time scale
Single comments in feedback from patients to the HFEA referred to difficulty in contacting the unit by telephone and this was also commented on by a patient providing feedback in the course of the inspection. The PR should consider monitoring telephone access to the unit.	To be monitored in the course of future inspections.
Not all patient information is fully compliant with the COP and relevant guidelines. The PR should ensure that there is a robust system for monitoring the content of patient information.	To be monitored in the course of future inspections.
At a time when there have been a number of staff changes and temporary staff members are working in the administration team, the centre should consider providing specific training or information to all relevant staff in the administration team outlining their responsibilities for incident reporting. The centre should also consider drawing up formal standard operating procedures to ensure that newly appointed members of the administration team are aware of all the responsibilities and duties of their posts.	To be monitored in the course of future inspections.
Not all members of staff interviewed were able to provide evidence of participation in annual mandatory health and safety training or basic life support training although subsequent to the review of the draft report the PR confirmed that this training had taken place. Members of the nursing team should ensure that records of training are made available for review in the course of future inspections.	To be monitored in the course of future inspections.

Proposed licence variations

None

Additional licence conditions and actions taken by centre since the last inspection

The previous licence was issued without any additional conditions or recommendations.

Changes/ improvements since the last inspection

Recommendation	Action taken
At the time of the interim inspection the centre had not completed the process of splitting the storage of samples cryopreserved for patients who had had treatment that may have impaired their fertility.	The centre completed the process in January 2006.
At the time of the interim inspection, the centre had not completed the process of contacting patients with sperm in storage to advise then of changes in the law as a result of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003.	Completed
Members of the embryology team were witnessing the transfer of embryos at the time of the fertility check on Saturday retrospectively.	Practice reviewed and revised protocol implemented.
An administrative incident was not reported to the HFEA within the prescribed timeframe.	Incident reported as requested
Sperm samples for more than one patient are in the flow hood while individual samples are processed. The centre should assess the risks of this practice and submit a copy of the assessment to the HFEA.	Assessment completed and submitted

Report of inspection findings

1. Organisation

Desired outcome: The centre is well-organised and managed and complies with the requirements of the HF&E Act.

Summary of findings from inspection
Evidence of:

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

Areas of firm compliance
The PR has responded to recommendations in the report of the previous inspection. Inspection documents and information requested in the course of the inspection were provided promptly. The centre appeared well organised to the inspection team. The centre adopts the clinical governance strategies of the Guy's and St Thomas' NHS Foundation Trust. In December 2005 the Trust was assessed as achieving level two in the clinical negligence scheme for trusts[2]. The centre has systems in place for clinical governance and quality management and attained International Standardization Organization (ISO 9001) certification in September 2006. The unit has appointed a quality manager who reported that 6 monthly reviews of the system are planned. Indicators of performance have been agreed in critical areas and it was reported that these will be monitored on a regular basis. The quality manager reported that prospective assessments will be carried out for all aspects of the centre's practice that give rise to risk. The centre maintains a log of incidents and this was reviewed by the inspection team. Incidents have been reported to the HFEA within prescribed timeframes and through the Trust's clinical governance system. Learning from incidents has been clearly demonstrated. A number of incidents were noted in the log that may have been of interest to the HFEA clinical governance team. The team agreed that when an incident or near miss incident occurs they would seek guidance from their HFEA inspector as to whether the incident should be reported to the HFEA. Documentation submitted to the HFEA and reviewed in the course of the inspection showed evidence of version control and periodic review.

[2] NHS Litigation Authority website

Clinical staff are available to patients out of hours and can admit patients as necessary. The average time to pay HFEA invoices over the last 6 months has been less than 60 days. The unit has a large number of staff and unexpected absences can usually be covered from the existing pool of employees. Contingency planning arrangements were not reviewed in the course of the inspection but the self assessment document submitted by the centre acknowledged that there could be improvements in contingency plans. This demonstrates awareness of the issue and progress in implementing improved contingency plans will be monitored in the course of future inspections.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Evaluation
No improvement required
Areas not covered on this inspection
Resource management Business planning

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:

- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Live birth rates
- Complaint handling
- Counselling facilities and services
- Patient feedback and satisfaction

Live Birth Rates

In the time period from 1 August 2005 to 31 July 2006 the centre provided 1057 cycles of IVF, ICSI and frozen embryo transfer treatment for 865 patients and 19 cycles of DI for 10 patients. This represents an approximate 8% increase in workload from the preceding year. Over the same time period the centre reported a 35% twin rate with no higher order pregnancies. No egg sharing or egg donation treatments were provided. Sixty five of the treatment cycles provided included pre-implantation genetic diagnosis.

Clinical pregnancy rates for the same time period and live birth rates for the preceding year are as follows.

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle: 01/08/05 to 31/07/06	28%	27%	34%	34%	0
Live birth rate per treatment cycle: 01/08/04 to 31/07/05	18%	10%	23%	10%	8%

Although it should be noted that these data compare clinical pregnancy rates with live birth rates, they do suggest that success rates are likely to show an increase in 2005-6 when compared to the preceding year.

These data have not been verified by the clinic and may be subject to change.

Analysis of HFEA held register data for the time period 31 March 2002 to 1 April 2005 and comparison with national statistics showed that the centres success rates were in line with national averages with the following exceptions:

- live birth rates following IVF and ICSI in patients aged under 35 and between 35 and 37 years were significantly higher than the national average;
- frozen embryo transfer success rates in patients aged less than 35 years were significantly lower than the national average;
- donor insemination success rates in patients aged between 35 and 39 years were significantly lower than the national average.

Areas of firm compliance
Inspection of patient records showed evidence of the completion of appropriate WOC assessment. Records are stored in filing cabinets in an area accessible by licensed personnel only. Archived records are stored electronically and the centre has written protocols for protecting and accessing the data. Evidence was provided that all staff (including temporary agency staff) are provided with relevant information relating to confidentiality issues. Staff are asked to sign a declaration confirming that they have received and understood the information. The centres complaints log was reviewed in the course of the inspection. The log showed that the centre had responded to complaints in line with locally set timescales. A counselling service is provided by three independent counsellors who can provide a total of 20 hours of counselling per week. It was reported that all three counsellors are members of the British Infertility Counselling Association, the British Association for Counselling and Psychotherapy and the British Fertility Society and that counsellors receive “in house” supervision organised by the Trust. The HFEA received feedback from 19 patients in the time covered by this report. Responses were very positive with 18 patients having compliments about the care they received and only two patients reporting that they had any complaints. Six of the 19 respondents (32%) said that counselling services are not accessible: nationally 31% of respondents make the same comment. However, the inspection team were satisfied that the centre’s counselling service is promoted in all relevant information and with the centres efforts to promote counselling and to make the service accessible. Patients can contact counsellors directly and can be seen by a counsellor very soon after requesting an appointment. The centre has implemented an opt out system in which patients are referred to the counselling team by a member of the clinical team and are then offered an appointment which they may then choose to refuse. Two patients currently receiving treatment at the centre agreed to meet with a member of the inspection team. Both reported satisfaction with the care that they are receiving, the provision of information and both were aware of the counselling service.
Areas for improvement
A small number of written comments in feedback to the HFEA referred to difficulty in contacting the unit by telephone. Similar comment was also made by a patient providing feedback in the course of the inspection and has also been the occasional experience of the centre’s HFEA inspector. The PR should consider gathering further feedback from patients on this issue and/or monitoring the response times to telephone queries.
Executive recommendations for Licence Committee
None
Evaluation
No improvement required
Areas not covered in this inspection

Choice of treatments
Privacy and dignity of patients
Donor selection
Egg sharing and surrogacy
Protection of children arrangements (for patients under 18yrs)

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
- Safe storage of embryos and gametes
- Safe equipment, servicing and maintenance
- Disposal of gametes / embryos

Areas of firm compliance
Premises appeared well presented and appropriate for purpose on the day of the inspection. Access to the embryology laboratory is restricted to licensed personnel by key pad entry system. Sperm production facilities were considered to be suitably private and appropriate for purpose. The centre has two cryostores both of which are fitted with a low oxygen level alarm. Dewars are fitted with low nitrogen level alarms and are connected to an auto dial system. Arrangements are in place to ensure that a member of staff is available to respond to a dewar alarm. It was observed that cryopreservation dewars are routinely monitored for nitrogen use and evidence of failure. Screened and unscreened cryopreserved material is kept in separate dewars and the centre has a spare dewar for emergency use. No discrepancies were found during a spot check audit tracking two embryos from records to dewar and from dewar to records and two sperm samples from records to dewar and from dewar to records. Evidence of annual maintenance of key pieces of laboratory equipment was seen in the course of the inspection. An annual audit of all cryopreserved material was completed subsequent to the inspection in December 2006. A number of discrepancies were observed where the computer inventory had not been updated. Following the audit, relevant documentation was reviewed to allow updating of the computer inventory to be recorded. Protocols for the disposal of gametes and embryos were reviewed by the scientific adviser who considered the procedures appropriate. The genetics laboratory has recently been awarded Clinical Pathology Accreditation (CPA) as required for laboratories carrying out PGD. Formal notification of CPA is awaited and it was agreed that a copy of the certificate would be forwarded to the HFEA on receipt.
Areas for improvement
None
Executive recommendations for Licence Committee

None
Evaluation
No improvement required.
Areas not covered on this inspection
Prevention of incidents/ accidents

4. Information

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

Summary of findings from inspection:

- Information provided to the HFEA
- Record keeping (including consents)
- Information for patients and donors

Outcome of audit of records
The documentation of witnessing was tracked in three sets of patient records. All the records showed documentation of relevant witnessing steps. Consent forms and documentation relating to welfare of the child assessments were reviewed in 10 sets of patient records. All consents were correctly completed and were compatible with treatment in nine sets of records. In one set of records the wishes of the female partner in the event of her death were unclear and it was agreed that clarification would be sought.
Areas of firm compliance
The centre has submitted only 3% of their treatment and outcome forms to the HFEA late in the time period from March 2005 to present. A report of the PGD treatments that have been provided by the centre has been submitted to the HFEA as required. Inspection of patient records showed evidence that the information provided to patients is documented, as is the offer of counselling. Patient records also contained evidence of appropriate screening prior to storage of gametes and embryos and of annual contact with patients with cryopreserved material in store.
Areas for improvement
Patient information was reviewed in the course of the renewal inspection in 2004 when it was considered largely appropriate. However, in the course of the interim inspection of 2005, information for donors or recipients of donor gametes was reviewed and a number of revisions recommended. These documents were reviewed again in the course of the current inspection. The information appears clear and comprehensive however a number of further clarifications and revisions are recommended. It is recommended that the documents entitled, "Removal of anonymity for donors, Donor sperm for IVF cycles -notes for patients and DI notes for patients" should be clarified to reflect: • that the male partner of an unmarried couple having treatment with donor sperm will have parental responsibility only if he registers as the child's father and his name is included on the birth certificate; • that non-identifying information can be provided before a child born as a result of treatment with donated gametes reaches age 18 years[3]. It is expected that patients will approach centres for non-identifying information in the first instance (see HFEA Update

[3] Chair's letter CH(04)07) states that licensed centres may give those who receive donor-assisted conception treatment non-identifying information about the donor used in that treatment.

Issue 5, November 2004);
- all of the screening tests that gametes providers are subject to and the limitations of the tests.

Information for egg donors should also be clarified to reflect:
- the circumstances under which identifying and non identifying information can be made available (see above);
- that donors and recipients can consent to the exchange of outcome information.

The information for patients receiving treatment with donor sperm should be revised as soon as possible. It is acknowledged that the centre has not provided treatment with donated eggs in the time covered by this report but should such treatment be provided, information should be revised as recommended. It is noted that relevant HFEA information is referenced in the centre's patient information.

The PR should ensure that there is a robust system for monitoring the content of patient information and for ensuring compliance with the requirements of the 6th Code of Practice and relevant guidelines.

Executive recommendations for Licence Committee
None
Evaluation
Some improvement required
Areas not covered on this inspection
Protocols Information management

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

- Staff competence, qualifications, training and CPD
- Recruitment and retention of staff
- Procedures in practice
- Clinical practice

Full time equivalent (FTE) staff

GMC registered doctors	8 (one team member on maternity leave at the time of the inspection)
NMC registered nurses	8 FTE (6 full time, 4 part time)
Nursing support workers	1
HPC registered scientists	4.6 FTE
Scientists working towards registration	2 (1 very experienced scientist awaiting recognition of qualifications gained outside UK.)
Counsellors	3 (providing a service for 20 hours per week in total)
Ultrasonographer	1
PGD team	16.4 FTE members of staff
Support staff (receptionists, record managers, quality and risk managers etc)	8 (1 member of staff on maternity leave at time of inspection and including 2 agency staff)

Highlighted areas of firm compliance
All clinical staff are registered with the General Medical Council. The training and induction file of a recently appointed member of the clinical team was reviewed in the course of the inspection. The file contained evidence of comprehensive induction and ongoing monitoring of practice and of participation in advanced life support training in February 2006. There was also evidence of GMC registration, CRB screening and a report of annual appraisal. The PR was also able to provide evidence of annual appraisal; participation in RCOG accredited CPD; GMC registration and personal professional indemnity insurance. All embryologists are registered with the Health Professions Council with the exception of two embryologists one of whom is in the final stages of acquiring registration and one of whom is awaiting recognition of qualifications gained outside the UK. All members of the nursing team are registered with the Nursing and Midwifery Council. Members of the nursing team perform ultrasound scanning and a rolling programme of training for relevant staff is underway. There have been a number of staff changes in the administration team and some cover is currently provided by agency staff. The centre has a robust system for ensuring that newly appointed members of the administration team are familiar with issues relating to

confidentiality and a recently appointed member of the team confirmed that she received appropriate induction training. An agency staff member provided evidence of appropriate recruitment including evidence of qualifications, CRB screening, vaccination and immunity status, and references from previous employers.

Annual reports of embryo biopsy and ICSI practice were submitted to the HFEA. The performance of all ICSI practitioners satisfies the requirements outlined in Chair's Letter CH(04)06 and embryo biopsy practitioners satisfy locally agreed performance indicators.

A member of the inspection team observed patients undergoing ultrasound scanning. It was considered that the patients were treated with dignity and that clear advice was provided.

A member of the inspection team observed laboratory procedures and confirmed that practices, including witnessing, appeared to be carried out appropriately and according to protocol.

In the course of the inspection, evidence of an audit of multiple birth rates was observed. Following the audit, the unit adopted a policy of performing single embryo transfers in selected patients. Approximately 30% of patients were receiving a single embryo transfers at the time of the inspection. No multiple pregnancies have been reported in patients who received a single embryo transfer.

The centre did not perform any three embryo transfers in patients less than 40 years of age in the time covered by this report.

Areas for improvement

The HFEA receives a large number of reports of incidents involving breaches of confidentiality from across the sector. At a time when there have been a number of staff changes and temporary staff members are working in the administration team, the centre should consider providing specific training or information to all relevant staff outlining their responsibilities for incident reporting. The centre should also consider drawing up formal standard operating procedures to ensure that newly appointed members of the administration team are aware of all the responsibilities and duties of their posts.

Not all members of staff interviewed were able to provide evidence of participation in annual mandatory health and safety training or basic life support training. This was also the case at the time of the interim inspection in 2005 but subsequent to the review of the draft report the PR reported that he had taken action to ensure that mandatory training is undertaken by all members of the team and that the training is documented. Staff, particularly members of the nursing team should ensure that records of training are made available for review in the course of future inspections.

Executive recommendations for Licence Committee

None

Evaluation

Some improvement required

Areas not covered on this inspection
Assessment of patients and donors Safe handling systems

Report compiled by:

Name…Debra Bloor…….

Designation…Inspector, HFEA……..

Date……18 December 2006……

Appendix A: Centre staff interviewed

Mr Yacoub Khalaf and ten other members of staff met with members of the inspection team.

Appendix B: Licence history for previous 3 years

Licence	Type	Valid from	Valid to
L0102/11/b	Treatment with Storage	01/10/2005	30/06/2008
L0102/10/a	Treatment with Storage	01/07/2005	30/06/2008
L0102/9/u	Treatment with Storage	31/01/2005	30/06/2005
L0102/8/z	Treatment with Storage	19/09/2002	30/09/2002

First licensed 1993

L0102/11/b, L0102/10/a,

No conditions

No recommendations

L0102/9/u

No conditions

Recommendations

- The centre should implement a protocol for contacting all patients with material currently in storage to advise them of the Deceased Fathers Act 2003.
- The Centre should produce laboratory protocols for the following procedures and these should be submitted to the HFEA within 2 months.
    - how frozen embryos/semen are allocated to storage locations and how the relevant records are completed.
    - of the special precautions needed for dealing with known infective samples to minimise risk between patients
    - semen analysis and, if applicable, sperm function tests or GIFT.
- The Centre should review its processes for auditing its patient records to ensure that all necessary consents have been completed and that the Centre should inform the HFEA, within 2 months, of the outcome of its on-going audit of patients' records.
- The Centre should also amend its patient information in order that the policy of transferring 2 embryos is made clear.

L0102/8/z

No conditions

Recommendations

- The centre should amend PGD patient information with the word 'unaffected' rather than normal
- The centre submits an annual report to the Working Group on New Developments in Reproductive Technology (WGNDRT) for consideration. The report should include the following information:
    - the patient category, the number of eggs collected, the number of embryos transferred and the outcome of the pregnancy including the number of sacs, embryos and babies.

Appendix C: Response of person responsible to inspection report

Centre Number……0102……

Name of PR……Yacoub Khalaf……..

Date of Inspection……5/12/06……..

Date of Response……17/01/2007……

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

The issues with training/induction highlighted in the report have been addressed. The patient information for patients receiving donated gametes is being reviewed to take into account the comments made at inspection. Telephone system is being addressed at a Trust level and would report back to you once this has been resolved

Licence Committee Meeting

14 February 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Guys Hospital (0102)
Interim Inspection

Members:
Emily Jackson, Lay Member – Chair
Ruth Fasht, Lay Member
Maybeth Jameson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Frances Clift, Legal Adviser
Chris O'Toole, Head of Research Regulation
Claudia Lally, Committee Secretary

Observing:
Sally Cheshire, Lay Member
Anna Carragher, Lay Member
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

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 (33 pages)
- no papers were tabled.

1. The papers for this item were presented by Debra Bloor, HFEA Inspector. Dr Bloor informed the Committee that this is a large unit with an active research programme and a well established PGD facility. The centre has appropriate facilities and well qualified staff and the patients whose views were sought seemed satisfied with the treatment they had received. The centre had responded well to suggestions and recommendations made at previous inspections, and only minor regulatory issues had been discussed at this inspection.

2. Dr Bloor informed the Committee that one such issue had been the requirement to formally record training received by nursing staff. The Person Responsible at the centre had been responsive to this suggestion. This was

noted by the Committee who agreed with Dr Bloor that it would be sensible to observe the new system at the next inspection.

3. Another issue noted by the inspection team was that the written patient information to patients donating or receiving treatment with donated gametes required to be re-written to bring it into line with the requirements of the Code of Practice. Dr Bloor informed the Committee that she had requested that this information be revised within 3 months of the inspection. This was noted by the Committee.

4. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Emily Jackson (Chair)