



## **Interim Inspection Report**

**The Lister Fertility Clinic  
0006**

**Date of Inspection: 11<sup>th</sup> October 2007  
Date of Licence Committee: 28 January 2008**

## CENTRE DETAILS

Centre Address	The Lister Hospital Chelsea Bridge Road London SW1W 8RH
Telephone Number	0207 730 3417
Type of Inspection	Interim
Person Responsible	Mr Hossam Abdalla
Nominal Licensee	Mary Power
Licence Number	L0006/13/a
Inspector(s)	Wil Lenton ( Lead, HFEA Executive) Allison Cummings (HFEA Executive) Grace Cunningham (External Inspector)
Fee Paid - date	N/A
Licence expiry date	28 <sup>th</sup> February 2010

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### **About the Inspection:**

This inspection visit was carried out on 11<sup>th</sup> October 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between August 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 to ensure that centres are working towards compliance with 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](http://www.hfea.gov.uk).

## Brief Description of the Centre and Person Responsible

The centre has been licensed since 1993 and offers a comprehensive range of treatments including pre-implantation genetic screening (PGS). It is a large centre which carried out in excess of 2000 treatment cycles in the last year. The majority of the centre's patients are private with a small minority of NHS patients. Sufficient numbers of appropriately qualified and competent staff are employed at the centre. There is an organisational structure in place which defines accountability, responsibility and reporting relationships. The person responsible is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act and has completed the PR Assessment workbooks. The centre is ISO 9001 accredited and has an extensive quality management system (QMS) in place. The centre successfully varied its licence in May 2007 in order to accommodate the requirements of the European Union Tissues & Cells Directive (EUTD).

## Activities of the Centre (01/01/06 to 31/12/06 HFEA Registry)

Licensed Treatment Cycles	IVF/ICSI	1634
	FET	376
	Egg Donation	112
	Egg Recipient	112
	DI	25
Unlicensed treatments	Ovulation induction	
Research	Yes	
Storage	Yes	

## Summary for Licence Committee

The overall level of compliance was considered to be good, however during the course of the inspection a number of regulatory issues were identified and are summarised below:

- The centre should ensure that the downstairs laboratory is kept secure when vacated by staff (Breach CoP7 – S.6.3.1)
- The centre should submit a completed sperm tank audit (Breach CoP7 – S.7.8.12(b))
- The centre should comply with CoP7 when replacing embryo's back in women <40 years (Non-compliance – G.8.5.1)
- The centre should ensure that consents are obtained from both partners (Non compliance – G.6.1.5)

It is recommended that;

- all third party agreements are in place and signed
- laboratory meetings take place at regular intervals
- training logs are more detailed and signed-off by a supervisor
- the witnessing SOP is amended to reflect practice
- the replenishment of all cryodewars is recorded in the hard log

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

### **Risk Assessment**

Following the inspection, the risk assessment as calculated via the HFEA Risk Tool is low at 16%.

**Overall judgement of the effectiveness of the centre**

<b>No Improvements required</b>	<b>Some Improvement required</b>	<b>Significant Improvement required</b>
	X	

**Evaluations from the inspection**

<b>Topic</b>	<b>No Improvements required</b>	<b>Some Improvement required</b>	<b>Significant Improvement required</b>
<b>1. Organisation</b>		X	
<b>2. Quality of the service</b>	X		
<b>3. Premises and Equipment</b>		X	
<b>4. Information</b>		X	
<b>5. Laboratory and clinical processes</b>		X	

## Breaches of the Act or Code of Practice

Breach	Action required	Time scale
The downstairs laboratory was left unattended/insecure (Breach CoP7 – S.6.3.1)	The centre should ensure that the downstairs laboratory is kept secure when vacated by staff	Immediately
A sperm tank audit had not been completed (Breach CoP7 – S.7.8.12(b))	The centre should submit a completed sperm tank audit	By 01/12/2007

## Non-Compliance

Area for improvement	Action required	Time scale
Three embryo's replaced in a woman < 40years (Non-compliance – G.8.5.1)	Adherence to CoP7	Immediately
Not all patients consents completed appropriately (Non compliance – G.6.1.5)	The centre should ensure that consents are obtained from both partners.	Immediately

## Recommendations

## Time scale

All third party agreements are in place and signed	3 months
Laboratory meetings take place at regular intervals	Immediately
Training logs are more detailed and signed-off by a supervisor	Immediately
The witnessing SOP is amended to reflect practice	Immediately
The replenishment of all cryostorage tanks to be recorded in the hard log book	Immediately



**Proposed licence variations**

None

**Changes/ improvements since last inspection (25/07/2006)**

<b>Recommendation</b>	<b>Action taken</b>
Appropriate storage measures are not in place for all patient records; some are currently being stored openly in an office	All notes are now stored in a secure locked area.
A 'paper only' audit of stored material has been performed;	Embryo tank audit completed and sperm tank audit due by December 2007
The centre should arrange that witnessing is always performed contemporaneously	Observed in practice
A protocol needs to be developed to cover what happens if a donor withdraws their consent for embryos in storage to be used in treatment.	SOP seen to be in place
Formal contingency arrangements should be put in place.	Document seen to be in place
All medical staff should attend an annual update of BLS.	Undertaken and certificates available
A written emergency protocol for responding to damaged storage vessels should be developed.	SOP seen to be in place
An alternative location should be found for the emergency trolley.	This has been carried out.

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

<b>C</b>	<b>N/A</b>
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## 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:

1. General organisation of the centre
2. Quality management system
3. Continual improvement
4. Corrective action
5. Preventive action
6. Internal audit
7. Establishment and review of contracts with third parties and transport
8. Transportation, labelling of shipping container and recall
9. Incident Reporting
10. Alerts
11. Notification of serious adverse reactions
12. Equality and Diversity
13. Risk Management
14. Donors
15. External reviews
16. Contingency arrangements

### Areas of firm compliance

Organisational charts provided on the day of inspection adequately defined working relationships and management structure. There appeared to be adequate numbers of appropriately qualified and trained staff in order to deliver the service to patients.

The centre has been ISO-9001 accredited since August 2005 and has a well established quality management system (QMS) in place. All the centres documented procedures are kept on an electronic drive accessed via the internal PC system which is password protected. A document control system is in place as evidenced by documentation sent prior to the inspection and documents examined on the day. Documentation is regularly reviewed either on an annual basis or in response to a change in protocol, which has been approved by the PR. Any documentation requested on the day of inspection was produced promptly.

Extensive evidence of regular minuted meetings were seen on the day of inspection. These included;

- Unit meetings
- Management & management review meetings
- Quality management meetings
- Risk assessment meetings
- Clinical meetings
- Nurses meetings

- Doctors meetings
- Laboratory meetings

Alerts are disseminated during unit meetings and amendments to protocols are instigated as required, with staff signing to confirm that they are aware of the updated protocol. Such an amendment to a SOP was observed during the laboratory visit.

An SOP for handling incidents was seen, which included performing risk assessments and corrective actions where necessary. An SOP is also in place for making changes to current practice in response to internal incidents, HFEA alerts and changing professional guidelines. This process of document revision is closely controlled by the PR/quality manager as part of the QMS. The centre has a risk management team which meets on a regular basis and many examples of meetings and assessments were seen on the day.

Third party agreements were seen to be in place with most companies which supply goods and services.

In order to facilitate inter-centre cooperation and review a meeting took place in June 2007 with centre 0102 (Guy's).

Contingency arrangements were seen to be in place with centre 0102.

#### Areas for improvement

Ensuring all third party agreements are in place and signed off.

#### Minor issues to be addressed

None

#### Areas not covered on this inspection

Equality & diversity

#### Evaluation

Some 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:

1. Live Birth Rates
2. Confidentiality and access to health records
3. Needs and requirements of users
4. Assessment of user satisfaction
5. Quality objectives and plans
6. Quality Manager
7. Quality Review
8. Counselling
9. Welfare of the Child
10. Monitoring and resolutions of complaints
11. Staff suggestions
12. Patient choice
13. Egg Sharing and Surrogacy

### Live Birth Rates (based on HFEA validated data 2003-5)

- IVF/ICSI success rates for all age bands are significantly higher than the national average
- FET success rates for all age bands are higher than the national average
- DI success rates for all age bands are lower than the national average

### Areas of firm compliance

HFEA licence, ISO accreditation and employers liability insurance certificates were prominently displayed within the main waiting area, together with details on the centre's complaints procedure, counselling service, quality policy and HFEA questionnaire.

Staff interviewed on the day were aware of confidentiality, privacy and dignity issues concerning patient care and these areas are included in the centre's compulsory induction course for all new staff.

Patient records were seen to be stored securely within an appropriately sized and secure medical records room.

The complaints log was seen on the day, with all but one issue resolved. The PR had written to the couple and the matter was in the process of being resolved.

A number of HFEA patient questionnaires had been received prior to the inspection with the large majority stating that they were happy with the treatment they had received at the centre.

A comprehensive counselling service evaluation and audit was provided with the pre-inspection documentation. This showed that for the year ending 31/05/07;

- Total clients seen = 779
- Number of couples = 446
- Number of individuals = 231
- Number of single women = 93
- More than one client session (2) = 73
- More than one client session (3) = 20
- More than one client session (4) = 5
- More than one client session (>5) = 8

This represented an increased uptake in the service of 18% compared to 2005/6, which was attributed to some extent by the change in legislation concerning donor treatment. A second counsellor is now in place in order to assist with the increased patient numbers, which means that the service is now available five days a week.

The results from the centre's own patient questionnaire covering topics such as;

- why they had chosen the centre ?
- how they were greeted on arrival ?
- had they been treated with dignity and respect ?
- ability to contact the centre
- sufficient information available at all stages of treatment

showed that the majority of patients were satisfied with the quality of service that they had received, with the only minor dissatisfaction being delays to appointment times. The centre had taken note of the results of the survey and was putting measures into place in order to improve this aspect of the service.

#### Areas for improvement

None

#### Minor issues to be addressed

None

#### Areas not covered on this inspection

None

#### Evaluation

No 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:

1. Any Changes
2. Suitable premises
3. Safe working with environment
4. Clinical facilities
5. Counselling facilities
6. Laboratory facilities
7. Storage facilities for gametes and embryos
8. Air quality
9. Staff facilities
10. Suitable equipment
11. Management of equipment and materials
12. Alarms
13. O2 alarms
14. Handling and manipulation of gametes and embryos
15. Dewars

#### Areas of firm compliance

On arrival at the reception area, located on the first floor of the centre, the inspection team were required to sign in for security reasons. The centre is located over two floors. The main facilities, such as;

- Patient waiting area
- Consulting rooms
- Scanning rooms
- Counselling room
- Medical notes storage
- Nurse administration room + office
- ET/treatment room
- Main laboratory
- Cryostore
- Men's production rooms

are all located on the first floor. There are stairs down to the main theatre suite, recovery area and a small laboratory utilised during egg collections.

All facilities were found to be well presented and fit for purpose. All critical patient-sensitive areas were seen to be secure.

Within the cryostore room all but one of the tanks were fitted with low-nitrogen alarms. This older type tank is unsuitable for such an alarm to be fitted and contains sperm samples which are nearing their storage expiry date. No new storage samples are placed in the tank and it will be decommissioned once all the remaining samples have been utilised/removed. The tanks are topped-up weekly and this is recorded in a log-book. A low oxygen monitor was present and a protocol in place detailing how staff should respond if the alarm was activated. A separate protocol is in place for security personnel within the

hospital to respond to out-of-hours alarms.

An external company presently provides air-quality monitoring. This was last tested in June 2007 at which time the air quality was recorded as grade B within laminar flow workstations and grade C within the rest of the laboratory, which is within EUTD guidelines. The laboratory manager has received financial approval to purchase a hand-held electronic particle counter by the end of 2007. Air quality is then expected to be measured and recorded every three months.

Service and maintenance documentation for laboratory equipment was seen to be up-to-date.

#### Areas for improvement

The log-book for liquid nitrogen replenishment should include the non-alarmed tank.

The door to the downstairs laboratory should be kept secured when the facility is vacated.

#### Minor issues to be addressed

None

#### Areas not covered on this inspection

None

#### Evaluation

Some improvements required.



#### 4. Information

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

Summary of findings from inspection:

1. Meetings and communication
2. Information management
3. Quality manual
4. Document control
5. Control of Records
6. Donor registration
7. Receipt of gametes
8. Home Procurement documentation
9. Traceability
10. Material donated to research
11. Coding
12. Information for users: Access to data
13. Tracking live birth events
14. Storage records
15. Information to the HFEA
16. Counsellor records
17. Import/export
- 18.3 embryo transfer
19. Donor Information
20. Storage and release of gametes and embryos
21. Storage forms
22. Anonymity
23. Labelling of packages containing procured gametes
24. Screening
25. Audit
26. Consents

#### Outcome of audit of records

Ten sets of patients notes were chosen at random. Five sets were used to assess witnessing steps within the laboratory and another five were reviewed generally.

From the general review of the notes it was found that some male partner WoC forms were missing and that some of the MT/WT wishes did not tie-up.

The PR and unit manager said that these notes would be reviewed and amendments made. It was also stated that the audit of patients notes would be improved in the future.

#### Areas of firm compliance

Within the main waiting area there were certificates showing;

- HFEA licence
- ISO 9001/2000
- Employers insurance liability

together with information giving details of the centre's;

- counselling service
- complaints policy
- quality policy

and copies of the HFEA patient questionnaire.

All patient information reviewed was clear and accurate and is held within the centre's QMS. This documentation is regularly reviewed and updated to reflect changing professional guidelines, patient feedback and/or HFEA alerts. All staff have access to this information via the secure IT network. Only named individuals can authorise the updating of patient information and/or centre protocols in keeping with the QMS document control policy.

Any information requested on the day was produced promptly via the QMS system.

#### Areas for improvement

The procedure for the taking and reviewing patient consents needs to be reviewed, together with the process for auditing patients notes.

On viewing the 3-embryo ET log it was noted that one woman <40 years had undergone a three-embryo ET. On reviewing the notes it was well documented that the woman was three months off her 40<sup>th</sup> year when the ET took place, had 8 previous failed attempts and had a history of poor embryo quality. (but nevertheless wanted a chance to bear her own genetic offspring – no pregnancy ensued)

#### Minor issues to be addressed

None

#### Areas not covered on this inspection

Import/export

#### Evaluation

Some 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:

1. Staffing Personnel Records
2. Criminal convictions
3. Initial /basic training and update training
4. Competence
5. Annual joint review
6. Continuing education and professional development
7. Procedures
8. Clinical Processes
9. Clinical treatment
10. Procurement, Distribution (including packaging and transportation), and receipt of gametes and embryos
11. Viral positive patients
12. Cross infection
13. Laboratory Processes
14. Selection and Validation of laboratory procedures
15. Screening
16. Emergency procedures
17. Handling and manipulation of gametes and embryos
18. Witnessing
19. Assuring the Quality of procedures
20. Participation in inter-Centre comparisons and inter-Laboratory comparisons

### Full time equivalent staff

GMC registered doctors	7
NMC registered nurses	9
HPC registered scientists	3
Scientists working towards registration	1 senior registered with ACE + 2 ACE diploma completed + 4 completing ACE diploma
Support staff (receptionists, record managers, quality and risk managers etc)	13

### Summary of laboratory audit

The latest frozen embryo audit undertaken in December 2006 was supplied. This was an extensive audit of fifteen cryostorage tanks. Only minor computer data entry errors were found. All embryo's are held with valid consents.

Ongoing sperm tank audit which is due to be completed December 2007

### Summary of spot check of stored material

Two cryostored embryo's tracked from records to tank  
One cryostored embryo tracked from tank to records

Two cryostored sperm samples tracked from records to tank  
One cryostored sperm sample tracked from tank to records

No discrepancies found

### Areas of firm compliance

All new staff undergo one weeks induction which includes mandatory training, prior to being allocated a mentor and working through a training plan. SOP's are acknowledged as being read and the log signed off by the trainer when deemed competent.

An SOP was seen describing competency checks, which are performed twice a year. Staff are asked to assess sperm and embryo quality and any re-training undertaken accordingly. It is hoped that in the future these checks will include staff at centre 0102 for external comparison.

An individual CPD file for the laboratory manager was seen to be ongoing and included online ACE assessments, a workshop on vitrification, HFEA conference and certificates from ESHRE courses.

Laboratory meetings are intended to occur every 6 weeks, but may be delayed due to work pressures. It was noted from minutes seen on the day that the last meetings took place in May and September 2007.

KPI's are measured on a regular basis. Daily checks are undertaken on ;

- Number of eggs collected
- Fertilisation rates
- Cleavage rates

Printouts from the QMS gave details of regular monitoring of KPI's. Audits are undertaken on a regular basis and coordinated by the quality management team.

Traceability is being addressed. There is an electronic log of all media supplies which come into contact with gametes/embryos and a hard log of other laboratory consumables. The centre has negotiated where possible an annual bulk supply of such items which facilitates standardisation. All critical equipment is CE marked.

Viral positive patients are treated, but any frozen material is stored offsite at another licensed centre which has appropriate facilities.

### Areas for improvement

All activities undertaken during training period should be dated, include brief details of activity eg number of eggs successfully collected and then signed off by trainer.

It was suggested that laboratory meetings be made more regular in future as they are an important means of minuted two-way communication.

Completion of cryostored sperm audit.
<b>Minor issues to be addressed</b>
Updating of witnessing protocols to include current practice. All witnessing steps are being performed appropriately but it isn't written into the SOP.
<b>Areas not covered on this inspection</b>
Validation of laboratory processes
<b>Evaluation</b>
Some improvements required.

Report compiled by:

Name.....Wil Lenton.....

Designation..... Inspector.....

Date..... 16/11/07.....

## Appendix A: Centre Staff interviewed

PR plus 5 other staff.

## **Appendix B: Licence history for previous 3 years**

### **2007**

*Licence Committee May 2007*

Variation of licence to incorporate the requirements of the EUTD

### **2006**

*Licence Committee 14 August 2006*

Renewal inspection 25 July 2006

*Licence Committee 7 June 2006*

Sperm import requests approved.

*Licence Committee 22 March 2006*

Licence continued and additional condition removed.

### **2005**

*Licence Committee 28 February 2005*

Representations against licence condition – LC agreed to vary the condition set by the previous licence committee to the following.

- That the centre carries out an audit of all of its records of material placed into storage from 1 January to 30 September 2004, noting any inconsistencies in consents. This audit should be carried out within 6 months and the results reported back to the Committee.

### **2004**

*Licence Committee 13 December 2004*

The Committee noted with serious concern that a high number of discrepancies and omissions were found in patient consent forms during the audit of notes at the inspection. They agreed to make a proposal to vary the centre's licence to impose the following condition:

- That the centre carries out an audit of all of its records over the past 12 months, noting any inconsistencies in consents. This audit should be carried out within 3 months and the results reported back to the Committee.

*Licence Committee 13 May 2004*

The Committee considered an incident at the centre and was satisfied that it should take no further action.

*Licence Committee 22 April 2004*

The Committee agreed to vary the licence to include laser and chemical assisted hatching. The Committee agreed that Charlotte Knight should be recognised as an embryo biopsy practitioner.

*Licence Committee 5 April 2004*

The Committee approved the centre's application to vary their licence concerning PGS protocol



*Licence Committee 28 January 2004*

The Committee deferred the decision to vary the centre's licence concerning their PGS protocol until the matter had been discussed with SCAG.

**Appendix C:**

**RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT**

Centre Number.....0006.....

Name of PR  
Mr Hossam Abdalla.....

Date of Inspection.....  
11 October 2007.....

Date of Response.....  
27 November 2007.....

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

Thank you for your interim report which we have received following the inspection on 11<sup>th</sup> October. You will be pleased to note that all of your recommendations have either been partially or fully implemented, as noted below:

- We are in the process of finalising all of our third party agreements
- The first organised laboratory meeting has taken place and ongoing meetings are scheduled to take place every 2 months
- Laboratory training logs are now being signed by the supervisor
- The Witnessing SOP has been amended appropriately
- All replenishment of cryo-storage tanks are recorded in a new hard log book
- A digital lock has been fitted on the downstairs laboratory door
- The sperm bank audit will be completed by 21<sup>st</sup> December 2007

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).

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

28 January 2008

21 Bloomsbury Street London WC1B 3HF

## MINUTES Item 7

### The Lister Fertility Clinic (0006) Interim Inspection

Members of the Committee:

Jennifer Hunt, Lay Member – Chair  
David Archard, Lay Member  
Sally Cheshire, Lay Member

In Attendance:

Stephanie Sullivan, Interim Head of  
Inspection  
Claudia Lally, Committee Secretary

Providing Legal Advice to the  
Committee:

Stephen Hocking, Beachcroft LLP  
Solicitors

Observing:

Ellie Suthers and Carol Horner, HFEA  
Inspectors

Simon Achonu, Beachcroft LLP (trainee)

Conflicts of Interest: Hossam Abdalla, Person Responsible at this centre declared a conflict of interest and was not present for this item. Other 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 (32 pages)
- one paper was tabled: response to report by Person Responsible dated 27 November 2007.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this centre has been licensed since 1993 and offers a wide range of treatments. It is a large centre which carried out in excess of 2,000 treatment cycles last year. Mr Lenton summarised the main issues of concern identified at the inspection, listed at page 8 of the inspection report. Two findings in the report constituted breaches of the Code of Practice:

the finding that the downstairs laboratory had been left unattended and that the sperm tank had not been audited.

2. Mr Lenton reported that on one occasion three embryos were transferred to a woman under 40 years old. The Committee noted the response by the Person Responsible on this issue which stated that a log was kept at the centre detailing the reasons for the transfers. The Committee agreed that it appeared to them that the three embryo transfer had taken place on the basis of a consideration of the specific clinical situation of the patient concerned. The Committee decided to remind the centre of the guidance given in the 7<sup>th</sup> edition of the Code of Practice:

G.8.5.1: Where the woman is aged under 40 at the time of transfer the centre should not transfer more than two eggs or two embryos in any treatment cycle, regardless of the procedure used.

The Committee also remind the centre that three embryo transfers will continue to be monitored at this and all other centres.

3. The Committee noted that the audit of the sperm tank was due in December and has been undertaken within the time scale requested.

4. The Committee noted the breaches and areas of non compliance identified in the inspection report. They also noted the prompt and helpful response from the Person Responsible and his assurances that the areas of concern identified in the report have either already been addressed or are in the process of being addressed.

5. The Committee agreed that the centre's licence should continue without additional conditions.

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