Renewal Inspection Report

Whittington Hospital NHS Trust
0258

Date of Inspection: 02 December 2008
Date of Licence Committee: 20 April 2009

Centre Details

Person Responsible Mr. Gidon Lieberman

Nominal Licensee

Centre name	Whittington Hospital NHS Trust
Centre number	0258
Centre address	Whittington Hospital NHS trust, Magdala Avenue, London, N19 5NF
Type of inspection	Renewal
Inspector(s)	Dr. Neelam Sood
	Dr. Vicki Lamb
Fee paid	Yes
Licence expiry date	June 2009
NHS/ Private/ Both	NHS

Index

About the Inspection:

This inspection visit was carried out on 2 December 2008 and lasted for 7 hours.

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 licence renewal 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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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

The Whittington Hospital fertility unit is a small centre that provides NHS funded intrauterine insemination (IUI) treatments to patients from the local area. The centre has been providing IUI for more than fifteen years.

The unit is open five days per week, Monday to Friday between 8:30 am to 17:00.

The Person responsible (PR) is registered with the General Medical Council and is a member of the Royal College of Obstetricians and Gynaecologists. He is employed as a consultant gynaecologist and obstetrician and has extensive experience within the reproductive medicine field.

Activities of the Centre[1] for the time period from July to December 2008

Intra uterine insemination (IUI)	314

Summary for Licence Committee

The centre has suitably qualified and experienced staff and largely appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment they have received.

A number of areas for improvement were identified in the course of the inspection relating to the following areas of practice:-

- validation of key processes and equipment;
- review of the quality management system;
- air quality monitoring;
- submission of outcome data to the HFEA;
- receipt of samples.

Subject to compliance with the recommendations made within this report, the executive recommend renewal of the centre's licence for a period of five years.

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

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, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
Laboratory procedures and critical processing procedures and critical equipment have not yet been fully validated. This is potentially a breach of S.7.8.3 of the Code of Practice (COP) and standard licence conditions A.10.13 A.11.11.	A plan for validation should be drawn up.This should take into account the particular needs of the unit and validation of those processes considered to be the most likely to impact on the quality of service should be prioritised.	Progress to be monitored at the next inspection.
A review of the quality management system has not yet been conducted. The quality manager reported that this is planned; Code of Practice standards 4.2.8 and 4.2.9 require that the centre management conduct an annual, review of the quality management system and all its services.	The quality management system should be reviewed in accordance with Code of Practice Standard 4.2.8 and 4.2.9	Progress to be monitored at the next inspection.
Air quality in the flow hood and background air quality in the laboratory in which gametes are processed has not been measured This is a breach of standard licence	In compliance with A.10.19 it must be demonstrated that gametes are processed in an environment of at least Grade C air quality with a background environment of at least Grade	Air quality monitoring to be implemented immediately and the results of monitoring to be logged. The HFEA should be

condition A.10.19.	D air quality. If testing shows that the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result. (G.9.4.5). Procedures for air quality monitoring should be validated so that it can be demonstrated that air quality is maintained in the interval between testing (A.11.11)	advised of the proposed timeline for compliance with this recommendation by 15 February 2009 and the results of air quality testing should be forwarded to the HFEA when they become available.
At the time of inspection, the PR had not provided information to the HFEA about the number of cycles of IUI provided or the outcomes of those treatments for the time period from 7 July 2008- 31 December 2008 as required by Directions D2008/6.	The PR should ensure that information requested is provided to the HFEA promptly in compliance with standard licence condition A.2.8.	Information to be submitted to the HFEA immediately.
The centre did not appear to have robust procedures for the receipt of sperm samples produced off site.	The PR should ensure that the centre has premises and facilities suitable for reception of samples in compliance with S.6.3.2. The PR should also ensure compliance with the requirements set out in A.9.2 – A.9.6. and A.8.13(g). The PR might wish to consider review of patient information to ensure that procedures for sample receipt are communicated to patients effectively.	To be monitored at the next inspection

Non-Compliance

Area for improvement	Action required	Time scale
Patients produce sperm samples off site as the centre has no facilities for sperm production. Guidance at G.2.3.1 of the COP states that centres should normally only use sperm which has been obtained directly from the provider. In exceptional circumstances the centre may use sperm produced by a man at home.	The PR should review the procedures for production of semen of site in consideration of the recommendations at G.2.3.1 and assess the risks of this procedure.	Progress to be monitored at the next inspection.
On review of the witnessing documentation in a sample of patient records, the documentation of witnessing of sperm collection and preparation steps was missing in two sets of records.	The PR should ensure that the centres has witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate, at the time each of the following clinical or laboratory procedure take place, in line with the recommendations of G.13.1.1. Where the centre chooses to adopt alternative witnessing procedures the centre should assess the risks of their procedures and document the rationale in line with G.13.3.1.	Procedures to be reviewed and any changes made as a result of the review to be implemented by 15 February 2009.

Recommendations

Area for improvement	Time scale

Changes/ improvements since last inspection

This is a report of the fist site visit to the centre.

Additional licence conditions and actions taken by centre since last inspection

N/A

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The Person responsible (PR) has completed the HFEA PR entry programme. The centre has an organisational structure with defined accountabilities and reporting relationships. A copy of the organisational chart was submitted prior to inspection. The PR has arrangements in place for managerial cover in his absence. He also stated that the unit has sufficient staff with relevant expertise that have been in post for many years. The centre has established third party agreements with suppliers and evidence of this was seen by the inspection team. The centre has a complaints policy which identifies the individual with responsibility for complaints and is readily available to patients. Patients interviewed in the course of the inspection reported that they were aware of the complaints procedures. The PR reported that there have been no complaints since beginning the service. The inspectorate was satisfied that the mechanisms for disseminating information to staff are effective. Copies of minutes of meetings are available in a file stored in the staff room. Staff interviewed during the inspection stated that they receive information and document updates via email. The centre has formalised a contingency agreement with another licensed centre to provide backup clinical and scientific facilities in case of an emergency. Procedures are in place for patients to contact staff out of working hours. Staff reported that they are encouraged to make suggestions to improve the service and that these are considered by the PR during team meetings. Members of the staff confirmed that they were aware of the HFEA alerts.
Areas for improvement

None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvement required
Areas not covered on this inspection
Incident management Risk management Payment of licence/treatment fees

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
TBA

Areas of firm compliance

The centre has a designated Quality Manager (QM). Progress in implementation and evaluation of a QMS is an on going process. There is an established a procedure for document control. A sample of documents reviewed in the course of the inspection included version number, page number and the name of the author. All documents had been reviewed within the previous 12 months.

The centre has a signed quality policy, which was last reviewed in November 2008. The quality policy outlines the centre's commitment to the provision of services which meet the needs of service users and the requirements of good professional practice.

The PR reported that patient satisfaction and complaints are audited on a regular basis.

The HFEA has received feedback from 5 patients who have received treatment at the centre since July 2007. All had compliments about the centre and expressed satisfaction with the quality of information provided and the clinic and staff. A patient interviewed during the course of inspection reported that she had been made aware of her treatment in detail and she considered staff to be polite and confident.

Areas for improvement

Although the PR reported that regular review of patient satisfaction is carried out, a more comprehensive review of the quality management system has not yet been conducted. The quality manager reported that this is planned; Code of Practice standards 4.2.8 and 4.2.9 require that the centre management conduct an annual, review of the quality management system and all its services.

Key performance indicators (KPI) are listed in the quality manual but performance in relation to these indicators has not been assessed. The centre reported that this is because of the limited activity levels of the centre.

Areas for consideration

In feedback provided to the HFEA by 5 patients who have undergone treatment at the centre since July 2007, 2 patients commented that they had complaints the service they received: two patients made negative comments about the facilities and staff in the imaging department where scans are sometimes carried out.

Although it is acknowledged that feedback has been received from only a small number of patients and that this may not be a representative sample, the PR may wish to consider targeting patient's views on this service in their assessment of patient satisfaction (S.6.1.1).

Executive recommendations for Licence Committee

The quality management system should be reviewed in accordance with Code of Practice Standards 4.2.8 and 4.2.9.

The Centre should establish documented procedures for audit in compliance with S.9.2.5: Quality indicators established for systematically monitoring and evaluating the Centre's assisted conception processes should be a particular focus for audit.

Evaluation

Some improvements required

Areas not covered on this inspection

All areas covered.

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
The centre offers outpatient only services within facilities used by gynaecology patients. The facilities are located off a main hospital corridor which opens out to a general waiting area. The HFEA licence was seen to be clearly displayed in the patient waiting area. On the day of inspection the premises and facilities appeared basic but well maintained and clean. The centre consists of two consulting rooms with one small sperm preparation laboratory and a shared waiting room. In an emergency the centres would be supplied by a back up generator situated in the main hospital. Patient notes are stored in lockable cabinets in the main consulting room with access restricted to licensed personnel.
Areas for improvement
Background air quality in the laboratory in which gametes are processed has not been measured This is not compliant with standard licence conditions A.10.19.
Areas for consideration
Patients produce sperm samples off site as the centre has no facilities for sperm production. Guidance at G.2.3.1 of the COP states that centres should normally only use sperm which has been obtained directly from the provider. In exceptional circumstances the centre may use sperm produced by a man at home. Patients are asked to sign a declaration that the sample was produced by them and there is a space for the signature of a staff member to confirm that the sperm sample has been correctly labelled A patient interviewed reported that she felt that there was a lack of clarity on the procedures to follow when attending the clinic with semen samples produced off site. The inspection team observed that there is no dedicated reception area for infertility patients as the unit is situated in the same corridor as the gynaecology ward and the reception desk is common for both the services.

Executive recommendations for Licence Committee
The PR should review the procedures for production of semen of site in consideration of the recommendations at G.2.3.1 and assess the risks of this procedure. The PR should ensure that the centre has premises and facilities suitable for reception of samples in compliance with S.6.3.2. The PR should also ensure compliance with the requirements set out in A.9.2 – A.9.6. and A.8.13(g). The PR might wish to consider review of patient information to ensure that procedures for sample receipt are communicated to patients effectively. In compliance with A.10.19 it must be demonstrated that gametes are processed in an environment of at least Grade C air quality with a background environment of at least Grade D air quality. If testing shows that the environmental air quality has or may have dropped below Grade D in the course of a procedure involving the manipulation of gametes, those gametes should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result (G.9.4.5). Procedures for air quality monitoring should be validated so that it can be demonstrated that air quality is maintained in the interval between testing (A.11.11)
Evaluation
Some improvements required.
Areas not covered on this inspection
Management of equipment and materials Staff facilities Counselling facilities (not applicable in IUI facilities) Storage facilities for gametes and embryos (not applicable in IUI facilities)

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Systems are in place to ensure that patients are provided with oral and written information. Although it is acknowledged that standard licence condition A.12.4 exempts basic partner treatment from the requirement to take account of the welfare of any child who may be born as a result of the treatment the centre has documented procedures for the assessment and evidence was observed that the centre follows their procedures for carrying out the assessment. A patient interviewed during the inspection stated that she was satisfied with the information that she had been provided with and this was echoed in the comments of five patients providing feedback to the HFEA. The patient also explained that she had been given the opportunity to ask questions throughout her treatment.
Areas for improvement
At the time of inspection, the PR had not provided information to the HFEA about the number of cycles of IUI provided or the outcomes of those treatments as required by Directions D2008/6.
Areas for consideration
Executive recommendations for Licence Committee
The PR should ensure that information requested is provided to the HFEA promptly in compliance with standard licence condition A.2.8.
Evaluation
Some improvement required.
Areas not covered on this inspection
Access to health records

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	2.0
NMC registered nurses	1.5
HPC registered scientists	0.2
Support staff (receptionists, record managers, quality and risk managers etc)	0
Counsellors	0.4

Areas of firm compliance

Currently two nurses have been trained in basic andrology, by the Quality Manger. They perform preparation of semen for insemination. Nursing staff have had their competency assessed by the QM regularly. The centre has procedures for the documentation of in house training and assessment. The PR reported that training records of staff are audited on a regular basis.

The PR reported that all staff have a job description and are engaged in a programme of continuous professional development (CPD). This was confirmed by the staff who were interviewed.

All nursing staff participating in licensable activity are registered with the Nursing and Midwifery Council.

The centre has documented clinical procedures for insemination and management of ovarian hyperstimulation syndrome (OHSS).

The centre has a system for ensuring traceability of consumables, and media. Batch numbers and expiry dates are logged on the laboratory internal quality control sheets.

Semen analysis is done in a microbiology laboratory which is CPA accredited.

Clinical procedures and protocols appeared satisfactory.

The executive was informed that lone working does not occur.

Areas for improvement

Laboratory procedures and critical processing procedures and critical equipment have not yet been fully validated. This is potentially a breach of S.7.8.3 of the Code of Practice (COP) and standard licence conditions A.10.13 A.11.11.

A witnessing protocol is in place however, on review of the witnessing documentation in a sample of patient records, the documentation of witnessing of sperm collection and preparation steps was missing in two sets of records.

Areas for consideration

In feedback provided to the HFEA by 5 patients who have undergone treatment at the centre since July 2007, only 2 patients commented that they had been made aware of the counselling service. Although section 12(1)(c) of the 1990 HF&E Act exempts basic partner services (IUI services) from the requirements of schedule 3 of the Act (which requires that patients are provided with an opportunity to receive counselling before giving consent) the centre does provide a counselling service and the PR may wish to consider targeting patient's views on this service in the assessment of patient satisfaction and/or reviewing procedures for making patients aware of the service.

Executive recommendations for Licence Committee

A plan for validation should be drawn up in consideration of Association of Clinical Embryologists (ACE) professional body guidelines. This should take into account the particular needs of the unit and validation of those processes and equipment considered to be the most likely to impact on the quality of service should be prioritised.

The PR should ensure that the centres has witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate, at the time each of the following clinical or laboratory procedure take place, in line with the recommendations of G.13.1.1.

Where the centre chooses to adopt alternative witnessing procedures the centre should assess the risks of their procedures and document the rationale in line with G.13.3.1.

Evaluation

Some improvements required

Areas not covered on this inspection

Counselling practice and counselling audit
Distribution and receipt of gametes
Storage of gametes and embryos
Screening of donors
Three embryo transfer

None of these areas of practice are applicable in an IUI facility.

Report compiled by:

Name……Neelam Sood/ Debra Bloor…….

Designation……Inspector…….

Date……15/01/2009……

Appendix A: Centre staff interviewed

PR and other four members of the staff.

Appendix B: Licence history for previous 3 years

An initial licence application pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 was considered on 20 June 2007 when it was decided to issue a licence for 2 years.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0258

Name of PR: Gidon Lieberman

Date of Inspection: 02/12/2009

Date of Response: 25/ 02/2009

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

Signed:

Name: Gidon Lieberman

Date: 25/02/09

1. 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).

There are no factual inaccuracies.

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

BREACH

Laboratory procedures and critical processing procedures and critical equipment have not yet been fully validated. This is potentially a breach of S.7.8.3 of the Code of Practice (COP) and standard licence conditions A.10.13A.11.11.

We have received further information from Dr Lamb concerning this matter and we are in the process of updating our procedures accordingly.

Air quality in the flow hood and background air quality in the laboratory in which gametes are processed has not been measured This is a breach of standard licence condition A.10.19.

We have had the air quality outside of the cabinet measures (12/2/09) and we are awaiting a written report.

A review of the quality management system has not yet been conducted. The quality manager reported that this is planned; Code of Practice standards 4.2.8 and 4.2.9 require that the centre management conduct an annual, review of the quality management system and all its services. The Quality review system has not occurred since we are a new licensed centre and normally this is done annually.

At the time of inspection, the PR had not provided information to the HFEA about the number of cycles of IUI provided or the outcomes of those treatments for the time period from 7 July 2008-31 December 2008 as required by Directions D2008/6.
This information is attached

The centre did not appear to have robust procedures for the receipt of sperm samples produced off site.

We already have this and it is incorporated in the IUI double checking and witnessing form, which had been comprehensively made for our centre. We will review our patient information to ensure this is reflected.

We are in discussions with the Trust to provide a dedicated area for sperm production on site

Non-Compliance

Patients produce sperm samples off site as the centre has no facilities for sperm production. Guidance at G.2.3.1 of the COP states that centres should normally only use sperm which has been obtained directly from the provider. In exceptional circumstances the centre may use sperm produced by a man at home.

See above – management business case underway to help secure comfortable facilities and to provide patient comfort and choice. Alongside we expect to improve staffing levels to enhance patient welfare.

On review of the witnessing documentation in a sample of patient records, the documentation of witnessing of sperm collection and preparation steps was missing in two sets of records.

We have reviewed this and expect such lapse will be monitored by us.

AREAS FOR IMPROVEMENT

Although the PR reported that regular review of patient satisfaction is carried out, a more comprehensive review of the quality management system has not yet been conducted. The quality manager reported that this is planned; Code of Practice standards 4.2.8 and 4.2.9 require that the centre management conduct an annual, review of the quality management system and all its services.
Key performance indicators (KPI) are listed in the quality manual but performance in relation to these indicators has not been assessed. The centre reported that this is because of the limited activity levels of the centre.

We are a new centre. We are aware of these points and as we stabilise and expand the service some of the KPI's will be measured.

Executive recommendations for Licence Committee

The quality management system should be reviewed in accordance with Code of Practice Standards 4.2.8 and 4.2.9.
The Centre should establish documented procedures for audit in compliance with S.9.2.5: Quality indicators established for systematically monitoring and evaluating the Centre's assisted conception processes should be a particular focus for audit.

This is an ongoing process and we expect with management support we will be able to have a greater focus on these areas.

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

HFEA Licence Committee Meeting

20 April 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Whittington Hospital NHS Trust (0258), Licence renewal

Members of the Committee:	
Anna Carragher, Lay member – Chair Jennifer Hunt, Senior Fertility Counsellor, IVF Hammersmith Hossam Abdalla, Clinical Director, Lister Clinic	Committee Secretary: Kristen Veblen, assisted by Claudia Lally Legal Adviser: Sara Ellson, Field Fisher Waterhouse

Declarations 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 (32 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this centre had provided NHS funded Intrauterine insemination (IUI) for fifteen years and had been licensed by the HFEA since 2007.

2. The Committee noted that the licence renewal inspection of the centre took place on 02 December 2008 and found that improvements were required relating to the following key areas of practice:

   - validation of key processes and equipment
   - review of the quality management system
   - air quality monitoring
   - submission of outcome data to the HFEA
   - receipt of samples.

3. The Committee noted the findings of the report and the statement by the Person Responsible setting out all the work being done in addressing the identified areas for improvement.

4. The Committee considered whether they were satisfied as to the suitability of the Centre's premises. The Committee agreed that, subject to the receipt of a written report concerning air quality, they had been satisfied of the Centre's premises. The Committee welcomed, the business case for a production room the centre had submitted to the Trust.

5. The Committee agreed that it was satisfied as to the use of suitable practices at the centre, based on the information provided in the report.

6. Further, the Committee wished to refer the Person Responsible to the 7th Code of Practice, Guidance on witnessing clinical and laboratory procedures, in particular at G 13.1.1. It noted the response of the Person Responsible concerning witnessing protocols, which did not include specific information regarding whether any need for change was identified and the implementation of any procedural change. The Committee noted that continued monitoring of witnessing protocols and any lapses was insufficient and that the responsibility of the Person Responsible was to ensure double witnessing took place.

7. The Committee also noted an apparent inconsistency in the results of service users' evaluation of the clinic in feedback collected by the HFEA, referred to on pages 11 and 12 of the report, and agreed that, in light of these comments, the Person Responsible should be given the opportunity to review this feedback and also consider a patient satisfaction survey.

8. The Committee noted that there were no issues regarding the character, qualifications or experience of the Person Responsible or his ability to perform his duties under Section 17 of the 1990 Act, and agreed that it was satisfied that the Person Responsible was suitable.

9. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination, was in receipt of a signed application and that the relevant fee had been paid. The Committee decided, given the number and scope of the breaches and instances of non-compliance, to grant a licence for two years.

10. The Committee agreed to recommend that an inspection take place within a year and that the focus of this inspection should include: incident management, risk management, payment of licence/treatment fees, management of equipment and materials, staff facilities and access to health records.

11. The Committee further agreed that they expected the outstanding areas for improvement identified at the December 2008 inspection to have been addressed.

Signed..Anna Carragher... Date..5.5.2009
Anna Carragher (Chair)