Inspection Report
EUTD License Application

The MacDonald Suite, Crosshouse Hospital, Kilmarnock, Ayrshire
Centre 0287

Date of Inspection 15 August 2007

License Committee Date 29th October 2007

Centre Details

Centre Name	Macdonald Suite, Crosshouse Hospital, Kilmarnock, Ayrshire
Centre Number	0287
Name of PR	Mr Clive Baird
Name of Inspectors	Mrs Gillian Walsh Inspection Chair HFEA Executive
	Dr Andrew Leonard Inspector (Science) HFEA Executive
	Dr Stephanie Sullivan Head of Clinical Governance HFEA
Date of Visit	15th August 2007
Focus	EUTD License Application
Fees paid	

With notice	**Yes**
Short Notice	
Unannounced	

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About this Inspection

The focus for this inspection was to assess the Centre's readiness for HFEA Licence Committee consideration of their Licence application under the European Union Tissue Directive. to conduct Intra Cervical and Intra Uterine Insemination with fresh, partner semen at Centre 0287, The Macdonald Suite, Crosshouse Hospital, Kilmarnock. The requirement for this centre to be Licensed with the HFEA is as a result of the implementation on the EU Tissue Directive on 5th July 2007.

The inspection visit was planned and lasted approximately 8 hours.

The inspection was conducted by Mrs Gillian Walsh, Dr Andrew Leonard and Dr Stephanie Sullivan.

During the inspection the Executive were introduced to Dr Clive Baird, PR, one medical Registrar, Senior Nurse, Staff Nurse, General Manager and the Quality Manager (lab). Dr Leonard was also introduced to key Laboratory Staff. Interviews took place with the staff throughout the day to discuss their progress towards achieving compliance with the European Union Tissues and Cells Directive (EUTD). Observations and discussions were conducted in assessment of the following areas:

How well the centre is managed and organised
The quality of the service for patients and donors
The suitability of premises, facilities, equipment and the efficacy of resource utilisation.
How information is managed, stored and provided to patients and to the HFEA
The standard of 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 were 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.

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

Brief Description, Risk Assessment, and Summary

The Centre is housed within a building which is part of Crosshouse Hospital, Ayrshire and Arran NHS Trust. This small unit shares facilities with other outpatient services, including Gynaecology, Cardiology and Cardiology testing. The Centre provides sub fertility diagnosis, ovulation induction and IUI treatment to NHS patients and their partners.

The Centre has strong affiliation with the tertiary fertility referral centre in Glasgow for training links and professional meetings.

Pre inspection assessment of this Centre generated a risk rating of 29% (amber) on the basis of their self-assessment application. This score was calculated against given EUTD criteria.

The Person Responsible, Mr Clive Baird, has successfully completed the HFEA Person Responsible Entry Programme, and is the Senior Gynaecology Consultant, first establishing a dedicated fertility service in the region in 1988.

Summary
This is a professional, friendly and caring unit, with a committed and enthusiastic PR who is keen to re-establish and grow a quality service in collaboration with the HFEA.

It was apparent that a lot of work is still required to be fully compliant with the requirements outlined in the Standards although from the evidence seen on the day of inspection, the staff should be congratulated on the time and effort they have made to date, and the finite resources available.

Executive Recommendation
License should be awarded subject to outstanding air quality, witnessing, labelling and traceablility issues being addressed.

The Centre should be visited once again within the next 10 months to validate progress.

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			✓
6. Evaluation and improvement		✓	

1. Organisation and Management Responsibility

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

The centre has a suitable Person Responsible who is supported by a management team capable of implementing an organisational structure appropriate for the licensable activities provided.

Summary of findings from inspection

- Leadership and management
- Organisation of the centre
- Quality Management
- Risk management
- Complaint and Incident management
- Documentation
- Third party agreement with non licensed entities
- Clinical governance

The Centre PR is in attendance at the Centre for a minimum of one, four hour session per week and is available to Centre personnel at all other working times when based away from the Centre in other parts of the hospital building. The Centre is housed jointly with general gynaecology outpatient services offering 2 infertility sessions per week, plus one joint infertility / andrology clinic per month. This small team are well established and have considerable experience of this element of infertility treatment. There appears to be good communication within the team and great commitment to provide a local, sensitive service of good quality to their couples.

Other services provided in this area are colposcopy, endometrial assessment, and urodymanics. Assisted conception (IUI) is offered at level two to Ayrshire couples over six days if required.

Dr Baird was able to demonstrate clear contingency plans for the emergency or urgent attendance of his IUI patients with another Trust Colleague. The General Manager for Women's Services has agreed to assume the responsibilities of PR in Dr Baird's absence.

A quality manager and been appointed.

Comprehensive risk assessment of the Centre had not been conducted at the time of inspection. Senior Nursing staff are still awaiting risk assessment training from the Trust. A member of the Pathology team is presently undergoing full risk assessment training and will be responsible for risk assessment of that department.

The Senior Nurse is responsible for inputting data onto the Trust Incident Database, Datex and is actively involved in a Trust wide incident analysis project. The Trust policy complies with HFEA requirements. Complaint handling is in accordance with Trust policy and incorporates HFEA information.

Third parties had not been fully identified and agreed throughout the Centre at the time of inspection.

The Centre reports into the Trust formal Clinical Governance agenda.

Five local protocols were provided for review. Electronic, centrally controlled generic Trust policies were not inspected.

Annual clinical audit reports on IUI outcomes for years 1995 to 2004 were available for inspection. Audit of 2005 / 6 treatments in progress.

Areas of firm compliance
PR meets the requirements for an appropriate PR - **S 4.1.4** PR has successfully completed the Person Responsible Entry Programme - **S.4.1.5** PR is regularly in attendance at the Centre and may be contacted easily by Centre Staff at other times and is aware of his responsibilities as PR – **S.4** PR has made appropriate provision for the assumption of PR responsibilities in his absence in accordance with Standard in accordance with standard **S.6.3.4** organisational chart and reporting structures are defined and staff appear informed **S.4.2.6** staff numbers and competencies appear appropriate for current activity levels **S.4.3** assessment of user satisfaction **S.9.2.1**
Evaluation following inspection
Some improvement required

Executive recommendations for improvement	**Time frame for completion**
The PR must actively pursue the formulation and completion of outstanding Third Party agreements with all associated parties in accordance with EUTD requirement Standard **S.4.1.10 S.4.2.10 S.7.3.2/3**	**Dec 07**
The PR must develop a quality policy for the Centre and support the QM in developing the Quality Manual and ensuring at the appropriate risk assessments are conducted irrespective of the Trust training lead time. **S.4.2. S.5.1 S.5.2**	**Dec 07**
Appropriate document control and validation to be implemented and audited as defined in **S.9.2.4/5 S.3.1.30** and required in Standards **S.5.1 S.5.2.3 and S.5.2**	**Dec 07**

Executive recommendations to Licence Committee
None at this time.

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:

- Staffing, competency and training
- Quality management system
- Confidentiality (including safe storage of patients' records)
- Patient records
- Consent
- Privacy and dignity of patients
- Patient feedback and satisfaction
- Counselling facilities and services

The Centre is staffed by one Consultant and one Registrar, supported by a small Nursing and HCA team, plus secretarial and administrative personnel.

All ultrasound scanning of IUI patients is either conducted by a member of the medical team or Senior Nurse, Frances Sheppard. (N.B new medical Registrars only undertake ultrasound scanning once they have completed an appropriate RCOG training programme and local supervised practice.

Staffing of the Unit is stable and currently at establishment with one nurse on maternity leave.

Staff were observed to have good access to and attendance on Trust mandatory training in Health and Safety, Basic and Intermediate Life Support, Fire and Manual Handling training. Additional / more formal Professional Development was sometimes more difficult to access due to geographical and domestic constraints. Many of the nursing staff have worked in this field for a number of years and are highly skilled, much of their training and ongoing supervision being experiential. All staff have a continuous professional development file.

Laboratory staff involved in the IUI process participate in regular NEQAS competency assessments and access to CPD is said to be good. The Pathology Department of which they are part has an established Quality Management System in place. The Biomedical Scientist interviewed was a HPC registered and a member of the British Andrology Society.

Staff asked were aware of their rights to conscientious objection and confirmed that team meetings happened regularly, the minutes for which were available at inspection.

The Senior Nurse has been nominated Quality Manager (QM). As this is an entirely new role to her, the QM is to be assisted by Carole Moore, a member of the Pathology team and is currently studying for formal Quality Assurance and Management qualification. A skeleton of The overall framework for the Centre's Quality Manual was available for inspection.

The team have put great time and effort into ensuring the environment in which couples discuss their treatment options or receive informal counselling, is private, calm and pleasantly furnished for their comfort. Treatment areas were also arranged with consideration to patient dignity and privacy. 'Engaged' signs were in evidence on both consulting and counselling room doors.

Patient satisfaction questionnaires have been introduced and are normally posted out to patients during or toward the end of their current treatment cycle. There were 11 available to view on the day of inspection, all of which contained positive comment about the Centre and treatment received. Staff

questioned said that as the Centre is so small, staff have close contact with their patients and quickly come to know if they are experiencing problems with the service and so are able to intervene swiftly to resolve matters.

Informal counselling is provided by experienced nursing staff in a pleasant, private environment. Though not specifically a requirement for EUTD, access to a counsellor had previously been available to all patients / couples but is no longer available at this Centre due to Trust economies. Staff felt that this was a great loss to the level of service they were able to offer their couples. This a small community and the provision of this service locally was considered of great value, couples often choosing not to make the considerable journey to Glasgow to see a formally trained Counsellor.

Areas of firm compliance
Staff numbers and competencies appear appropriate for current activity levels and are aware of their right to conscientious objection. **S.4.3 S.6.2.1 /2 / 3**

Executive evaluation following inspection	
Some improvement required	
Executive recommendations for improvement	**Time frame for completion**
The Quality Manager and Lab Quality Manager are to continue to work together on this significant piece of work, to develop the role profile and unite the elements of Quality Management in the Centre to reflect Standards **S.3.1.9, S.4.2.3 & S.4.2.4**	**Dec 07**
Further development of training programmes and evidenced competency assessments are required to demonstrate competency and validate experiential learning and reflect the requirements of Standards **S.6.2.7 /8/9** and **S.6.2.11**	**Feb 08**
Executive recommendations to the License Committee	
No further recommendations at this time	

3. Premises, facilities and resource management.

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

Summary of findings from inspection:

- Quality management system
- Premises and facilities for staff and patients
- Receipt, processing and handling of gametes
- Equipment, servicing and maintenance
- Prevention of incidents/ accidents

General and Clinical

The Centre is accessed via the main outpatient services entrance, adjacent to the main hospital building. This entrance is locked out of hours. The waiting area is shared by fertility patients, partners and general gynaecology patients. The out patient schedule is such that the clinic areas are currently quiet when fertility clinics are scheduled. A good standard of general information was available in this area, including information relating to 'an excellent Infertility Support Group, which has been awarded National Lottery funding and is part of the UK National Infertility Network. More specific fertility information was not on show, staff preferring to give specific information at the time of consultation when a treatment path is proposed.

Patient toilets positioned off the waiting area were private and clean. Marginally away from this area was a 'local' reception area where fertility patients are received. A room for the production of semen was located off this area and noted to be clean, private and adequate for use. A consultation room and room in which patients / coupled are counselled was noted to be comfortably furnished, calm and private. Consultation rooms were also noted to contain comprehensive written fertility information.

It was noted that the treatment room is private and spacious and appeared to be well equipped. The treatment couch was screened by a curtain and the door could be locked. An 'occupied' sign also illuminates when required.

The facilities observed were clean, adequately furnished and appropriate for the intended use. Service continuity in the event of a building failure was that patients could be seen in an alternative clinic and treatment area within the hospital. More complex arrangements would require the service to be wholly or partially relocated to Glasgow Royal Infirmary pro tem.

In the event of an electrical failure, the Centre and Laboratory are supported by the main hospital's emergency generator, which is tested monthly.

Equipment and consumable supplies purchases are made in accordance with the Trust purchasing policy. The Trust is working towards complete CE mark equipment compliance.

Equipment maintenance is managed by the Trust Medical Engineering Department and are also responsible for PAT testing and scheduled preventative maintenance provided in house or by arrangement with specialist equipment providers. Maintenance schedules are not held within the Centre and so could not be observed.

Staff indicated that they were aware of what to do in the event of equipment breakdown but this was not documented.

The cleaning and decontamination of equipment observed and on questioning appeared to be in accordance with good practice and manufacturer instructions.

Third Party Agreements for both equipment and consumables used in the assisted conception process which have the potential to influence the quality and safety of gametes were not yet in place at the time of inspection.

Contingency for key equipment breakdown was largely covered by back up equipment being available from elsewhere in the Trust. Where key equipment is not replicated e.g certain laboratory equipment, the service would be suspended.

Health and Safety risk assessments were not inspected.

Areas of firm compliance
The Clinical facilities were assessed by the Executive to accessible and appropriate for the activities proposed under this license. **S.6.3/4/5** Equipment and materials in place meet the requirements of EU Directives 93/42/EC Medical Devices **S.6.4.1**

Executive evaluation following inspection	
Some improvement required	
Executive recommendations for improvement	**Time frame for completion**
Third Partly Agreements to be agreed and in place without delay. **S.7..8.18 & S.7.8.14**	**Nov 07**
Outstanding measures to insure appropriate air quality and the overdue preventative maintenance of equipment required to be addressed without delay.**S.7.8.5 S.6.4.2 / 3 / 4**	**Dec 07**
N.B The PR may wish to consider whether the laboratory services provided by the Trust to the Centre should be classified as a Third Party Service for which an agreement is required. Clarification can be sought on the HFEA website under EUTD HFEA Third Party Guidance Note.	
The PR and Quality Manager are to conduct a training needs analysis of clinical staff and facilitate relevant clinical professional development to demonstrate staff competency.	**Feb 08**
Executive recommendation to Licence Committee	
None at this time.	

4 Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA, records are complete and stored securely, accessible only by appropriate personnel.

Summary of findings from inspection:

- Information management
- Information to patients
- Consent
- Protocols
- Control of records

Five local protocols were provided for review:

Pre-treatment discussion
Obtaining signed consent
Protection of privacy, dignity and confidentiality
Infection Control
After care

Other documents submitted for review we:

Organisation plan for Children, Women and Sexual Health Services
IUI treatment criteria
Patient leaflet on confidentiality
Annual Audit figures for IUI from 1995 to 2004

A random selection of patient records were also presented and were examined by the Executive.

In summary:

some of the documentation was found to be out of date, required proof checking for inaccuracies and were not verified or version controlled. Electronic, centrally controlled generic Trust policies were not inspected

a number of the patient records examined were incomplete either in detail or key information being absent altogether. Once case was noted to have exceeded the Centre's guideline for continuation with IUI when a high number of follicles is identified.

Patient notes from that morning's clinic where note to be assembled on a trolley alongside the consultation rooms. Medical records for current patients in treatment are stored in lockable cabinets in the treatment room. These cabinets were not locked at the time of inspection but the outer door was prior to our entry.

When questioned, staff were largely aware of the required length of time fertility health records are to be stored.

Patients are given information both verbally and in writing. Information regarding treatments offered was seen to be available in consulting rooms. Treatment choices are discussed at consultation and additional written information offered then. Pre treatment interviews with experience nursing staff are conducted and couples are given sufficient time to discuss there treatment options.

A consent policy is in place but does not reflect who may obtain consent and should be updated to reflect the requirement for the need for competent, valid consent, in writing or otherwise.

Seminal analysis audit form details are passed to the Pathology Department and entered onto Telepath, the Pathology results database, accessible by hospital wide clinical staff via the Trust intranet, this presents a possible breach of confidentiality.

Areas of firm compliance
The Centre has a consent policy in place but needs some review to reflect current guidelines and relevant HFEA guidance. Individuals are given verbal and written information and are given the opportunity to seek further advice and guidance from clinical staff. Welfare of the child born as a result of treatment is considered. Although not a requirement for this license, individuals and couples are offered well informed but informal counselling in a calm and private environment. Should more formal counselling be indicated or requested referral on is facilitated.

Executive evaluation following inspection
Some improvement required

Executive recommendations for improvement	**Time frame for completion**
Health records management procedures must reflect the control of access to and security of health records. **S.6.5 & S.7.2.1/2**	**Immediate**
The Centre must ensure that all documentation and records of the Assisted conception process are complete and conform to general Requirements of the HFEA standards, CoP 7th ed. **S.5.2 S7.1.4 & S.7.3.3**	**Immediate**
Consent policy to be reviewed to reflect current best practice and authority to seek consent and reflects all elements of standard **S.7.5**	**Dec 07**
Executive recommendation to License Committee	
None at this time.	

5 Laboratory and clinical practice

Desired outcome: The Centre's laboratory and clinical practice shall comply with current professional guidelines, legislation and regulations.

Summary of findings from inspection:

- Facilities and environment
- Receipt, processing and handling of gametes
- Protocols
- Control of records
- Quality Management

Semen preparation for IUI is currently performed within a designated laboratory area within the Centre. Ownership and maintenance of equipment and materials used in this area is split between the Centre and the Trust Pathology Department. The Executive was informed by the Semenologist that consequently, not all equipment in this area is covered by the Pathology Department maintenance contract or was inspected as part of the Pathology Department's CPA accreditation. It was observed that this equipment was now overdue both maintenance servicing and electrical safety testing. It was acknowledged by the Executive that this may be due to the fact that the service has been inactive since July 2007 subject to Licensing.

Air Quality
Air quality in the semen preparation area has been externally assessed by a professional contractor, the results of which were observed by the Executive and confirmed to pass the Grade D criteria. The centre informed the executive that they have planned for a Class II cabinet for this area to provide air quality of the appropriate standard.
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Traceablity
Batch numbers of material used in semen preparation referenced to each patient are stored in the Pathology Laboratory. It was however noted that only the date on which a batch is changed (not specific to a patient) is recorded. Materials used in the treatment room for IUI are not currently recorded.

Witnessing
The Scientific Inspector discussed the witnessing steps in the laboratory with the Seminologist and with nursing staff. The Executive observed that the steps in sperm processing which were witnessed are done well but is not inclusive of all steps required.

Samples are given to the Lab for processing are labelled and accompanied by a request form and addressograph labels with the person's name, address, date of birth, hospital number and 'CHI' number (locally derived clinic number). A lab number is allocated, generated by the Path. Lab computer which has been generated ahead of time. Information from the request and the Path Lab number are transferred to the seminal audit form. This is not is not currently witnessed. During processing the sample is identified by the person's name and laboratory allocated number. The prepared sample is checked for name and lab number labelling before release to the IUI nurse. **The** was identified as a risk on inspection as the sample prepared for insemination leaves the laboratory area identified by the individual's name and lab number only. At the point of insemination the clinical staff have only the name on the vial to compare with other records / name band etc. as they do not have record of the pathology generated number. This presents greater risk with the incidence of same/similarly named patients. The staff member asked did not believe there was a policy for managing same / similarly named patients in place.

The Scientific Inspector was shown the Cytology Unit risk assessment fill which included SOP's for sperm sample preparation but not a laboratory risk assessment.

The Pathology Department has a well developed Quality System / Manual which operates separately from that of the Centre.

Risk assessments and third party agreements were still in progress at the time of inspection.

Areas of firm compliance
Laboratory staff are participating in quality audit, CPD and NEQAS assessment

Executive evaluation following inspection	
Some significant improvement required	
Executive recommendations for improvement	**Time frame for completion**
Third Partly Agreements to be agreed and in place without delay. **S.7..8.18 & S.7.8.14**	**Nov 07**
Witnessing is not comprehensive and does not contain the required witnessing steps as required. This process must be risk assessed and a robust SOP encompassing both clinical and laboratory processes must be formulated. **S.7.8.5 &15**	**Dec 07**
Review of clinical and laboratory protocols and processes to ensure traceability of products, materials and gametes and robust identification and labelling at all stages of the process, including those produced at home.	**Dec 07**
Confirmation of consent must be confirmed by lab personnel prior to laboratory processing. **S3.1.28, S.7.3 & S.7.7.9 S.7.8.4**	
A robust policy for the management of same name / similar name patients is to be developed and communicated to all parties.	**Nov 07**
The Centre's laboratories (or are third party to) must establish and conform to documented laboratory procedures must specific to the receipt, processing and handling of gametes which current, risk assessed and validated as per **S.7.8.1, 2,3 & 4.**	
Outstanding measures to insure appropriate air quality and the overdue preventative maintenance of equipment required to be addressed without delay.**S.7.8.5 S.6.4.2**	

Executive recommendation to License Committee
Evidence of air quality control and robust, risk assessed witnessing and traceability procedures to be in place through out the IUI process prior to a license being awarded.
Labelling is to be more robust, to include 3 points of identification through all stages prior to license award.

6 Evaluation and improvement process

Desired outcome: The Centre shall plan and implement Evaluation and improvement processes to demonstrate a quality service which meets required standards which meets the needs of the users.

Summary of findings from inspection:

- Quality Management System
- Internal audits
- Use of audit information
- Risk assessment and preventative action
- Quality Management

Laboratory.

A system of audit and evaluation was seen to be in place as part of the existing quality management programme. Laboratory staff participate in regular NEQAS assessments.

The main Pathology Department is currently undergoing CPA accreditation inspection but does not currently include the Laboratory function within the Centre.

Evidence of regular and comprehensive risk assessment and evaluation was not in place but the Executive was informed that specific training was currently underway/

Pathology Department policies, documentation and standard operating procedures were largely observed to be current, version controlled. Evidence that staff had confirming staff had read the documents was observed. Risk assessment, policies relating directly to the handling and preparation of semen for analysis and insemination were absent or poorly defined.

Clinical Area.

Documents relating to the audit of clinical outcomes were seen on inspection and covered the period form 1995 to 2004. Audit of subsequent year's results is currently in progress.

A patient satisfaction survey has been implemented but results not audited as yet.

Staff Clinical Professional Development has been limited until now due to Trust access, funding and appropriate CPD opportunities.

Complaints and patient satisfaction audits are planned.

Adverse incidents / near miss events are currently dealt with in accordance with Trust Policy. HFEA requirements for incident reporting and Alert information have been implemented.

There is currently no opportunity for inter centre professional comparisons.

The Centre fees into the Trust Clinical Governance programme.

Areas of firm compliance
Clinical outcome audit is well established. Patient satisfaction and feedback assessment has begun. **S.9.2.1** The Centre actively participates in the Trust wide incident action programme, reporting and incident

handling are in line with HFEA requirements. **S.9.4.1/2/4/5**

Executive evaluation following inspection	
Some improvement required	
Executive recommendations for improvement	**Time frame for completion**
The clinical team are to be encouraged to forge links with similar Centres to share learning and professional comparison and seek To develop inter centre / lab comparisons. **S.9.2.5**	**Feb 08**
The Quality Manager must develop a comprehensive audit programme Comprising the elements to be audited, audit criteria, frequency and methods To be employed, determine who is equipped to conduct the audits and how Information gained with be reported and acted upon. **S.9.2.5**	**Feb 08**
Executive recommendation to License Committee	
None at this time	

Next steps

The PR will review the content of this report, identifying any factual inaccuracies and respond in accordance to any progress made to date.

Report completed by

Signed

Name Gill Walsh

Designation Inspector

Date 10 September 2007

Appendix A:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……..

Date of Inspection……..

Date of Response……

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

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 A of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

29 October 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Crosshouse Hospital (0287)
Initial Licence Application

Members of the Committee:

Jennifer Hunt, Lay Member – Chair
David Archard, Lay Member
Sally Cheshire, Lay Member
Neva Haites, Professor of Medical Genetics, University of Aberdeen, present via conference telephone

Observing:
David Gomez, Legal Adviser to the Authority

In Attendance:

Trish Davies, Director of Regulation / Deputy Chief Executive
Stephanie Sullivan, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Heledd Lloyd-Jones, Morgan Cole Solicitors

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

The following papers were considered by the Committee:

- papers for Licence Committee (47 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre is a small gynaecology clinic attached to Crosshouse Hospital, Ayrshire and Arran NHS. The centre provides sub fertility diagnosis, ovulation induction and IUI treatment to NHS patients. The clinic is well established but has not been carrying out treatments in the time following 5 July 2007, at which point, on the implementation of the EUTCD, the centre became licensable under the Human Fertilisation and Embryology Act 1990.

2. Mrs Walsh drew the Committee's attention to the Executive recommendations for improvement listed in the inspection report. She informed the Committee that the centre have responded very positively to these recommendations and has been busy since the time of the inspection in implementing the recommendations

made. The Committee noted this and asked Mrs Walsh to update them on recent action by the centre.

3. Commenting on the recommendations in the report under the heading "Organisation and Management Responsibility" Mrs Walsh informed the Committee that third party agreements are now in place, that formal risk assessments are now being carried out and that the centre is making good progress with developing a Quality Management System and implementing document control procedures.

4. Under the heading "Quality of Service" Mrs Walsh informed the Committee that progress is being made on the requirements to develop the Quality Manager role, to validate previous training and to develop competency assessments. The Committee noted that the time frame for completion of this development is February 2008.

5. Mrs Walsh informed the Committee that good progress was being made in relation to the recommendations under the heading "Premises, facilities and resource management". In particular, new air quality equipment had now been installed and commissioned. In response to a question by the Committee, Mrs Walsh agreed to request an air quality report from the centre.

6. Under the heading "Information", Mrs Walsh informed the Committee that the two recommendations for immediate implementation have now been addressed. These were the recommendation to tighten health records management procedures and to complete patient documentation and information to required standards. The recommended review of consent policy is also underway.

7. In considering the recommendations under the heading "Laboratory and clinical practice" the Committee noted with concern that the centre's witnessing procedure does not currently conform with HFEA Directions 2004/4. The Committee agreed that it was essential that this recommendation is implemented prior to the start of any licensable treatments at the centre. This was also considered essential in relation to the processes to ensure traceability , identification and labelling procedures. Mrs Walsh informed the Committee that the centre has now addressed the recommendation on procedures for confirming consent; in addition, the equipment referred to in this section has now been serviced in line with recommendations.

8. In relation to the centre's evaluation and improvement process, Mrs Walsh confirmed that the centre now has a more comprehensive audit programme.

9. The Committee welcomed the centre's swift response to the recommendations made at the inspection visit. They agreed however that all those recommendations in the report which were given a time frame for completion of December 2007 must be implemented by the centre prior to the

commencement of licensable treatment. The Committee agreed to grant a two year licence to the centre with a start date of 1 December 2007. They stated that this licence should not be offered to the centre until such time as the Executive has obtained written assurance from the Person Responsible that all outstanding matters due to be addressed by December 2007 have been resolved.

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