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Renewal Inspection Report

Crosshouse Hospital, Kilmarnock

Centre 0287

Date of Inspection: 17 June 2009

Date of Licence Committee: 14 October 2009

Centre Details

Person Responsible	Dr Clive Baird
Nominal Licensee	Ms Joanne Sharp
Centre name	Crosshouse Hospital
Centre number	Centre 0287
Centre address	MacDonald Suite Crosshouse Hospital Kilmarnock Ayreshire Scotland
Type of inspection	Treatment Licence Renewal
Inspector(s)	Mrs Gill Walsh Mrs Sarah Brain
Fee paid	Renewal fee paid
Licence expiry date	30 November 2009
NHS/ Private/ Both	NHS

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About the Inspection:

This inspection visit was carried out on 17 June 2009 and lasted 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 centre is located within a stand alone building on the campus of Crosshouse Hospital which is the principal general hospital for North and East Ayrshire, Scotland.

The Person Responsible (PR) is a senior Consultant Obstetrician and Gynaecologist for the Trust and has been on the specialist register of the General Medical Council (GMC) for Obstetrics and Gynaecology since May 1996.. The PR has held this position since December 2007 having successfully completed the HFEA Person Responsible Entry Programme (PREP).

The Centre provides services for the investigation and diagnosis of sub-fertility, ovulation induction and intra uterine insemination (IUI) treatment to NHS patients and their partners from the surrounding districts.

The centre is open for routine patient appointments between 09:00 and 17:00 hours Monday to Friday and 09:00 to 12:00 Saturday for treatment only if required.

Activities of the Centre[1] for the time period from 7 July 08 to 31 December 08

Intra uterine insemination (IUI)	42

Summary for Licence Committee

In considering overall compliance, the executive considers that it has sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR has discharged his duties under Section 17 of the HFE Act. and that those acting under the supervision of the PR are suitably trained and qualified for their designated roles. Patients report satisfaction with the treatment that they receive
- the executive believes that the premises and equipment inspected are suitable for the treatment procedures for which the centre is licensed
- the centre has been proactive in the development and implementation of a quality management system
- the executive is satisfied that, overall the centre demonstrates suitable practices in

[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.

respect of air quality, laboratory, clinical and administrative procedures conducted in relation to licensed treatments.

- the centre has submitted appropriately completed documentation in application for renewal of their licence and has submitted fees to the HFEA in accordance with requirements.

- improvements should however be considered relating to the following aspects of the centre's practice:

    - Timely submission of licensed activity data to HFEA
    - Formulation and execution of an internal audit schedule which reflects the centre's activities
    - The availability of professional development and update training and the assessment of staff competency
    - Access to appropriate clinical professional development for staff
    - Revision of existing third party agreements.
    - Revision of witnessing procedures to include the time witnessing stages are observed
    - Validation of laboratory equipment, practices and processes

The executive recommend that progress in addressing the issues outlined above should be made within the timescales specified.

The executive considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional condition. This should be subject to compliance with the recommendations proposed in this report within the prescribed timeframes.

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
Validation		

Validation of critical equipment and key processes and procedures is not in place, however evidence of a number of audits having been conducted and partial validation was seen. Ref: S.6.4.2 and S.7.8.3 of the COP and standard licence condition A.11.11.	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of key equipment and processes considered to be most likely to impact on the quality of the service. Validation of all critical equipment should be completed by March 2010	The plan for validation should be submitted to the HFEA. Progress towards full implementation of the plan to be monitored in the course of the next inspection
Competence Assessment Staff training and competency assessments are not being adequately reviewed or documented. Staff training folders across all disciplines provided at inspection contained no evidence of initial or reviewed competency assessment and sign off of critical skills. A.10.11	The centre should establish documented procedures for staff management that ensure that all staff have competence assessment. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. The PR must ensure and document that each individual: has demonstrated confidence in the performance of their designed tasks,.	To be monitored in the course of next inspection.
Professional Developlment and Update Training It became evident on interview and examination of training logs for staff currently in post that access to appropriate professional development resources and update training is largely absent. A.10.11.	Staff should be given adequate opportunity to access appropriate training and professional development which is updated as required when procedures change or scientific knowledge develops.	To be monitored in the courses of the next inspection.
Submission for treatment data to the HFEA The centre has not submitted annual licensed treatment data D.2008/6	The PR should ensure that an annual return is submitted to the Authority no later than 28 February in each calendar year in accordance with General Directions D.2008/6	The annual return for this period outstanding should be submitted by by 27 July 2009.
Third Party Agreements Not all third party agreements contained the requirements specified in standard licence	The PR should review the content of third party agreements against the requirements of the	To be monitored in the course of the next inspection

condition A.5.4 and G.2.1.2.	standard licence condition A.5.4 and CoP G.2.1.2 and update the agreements accordingly.	
Audit Schedule Only a small number of internal audits have been conducted **S.9.2.4/5**	The centre should establish an internal audit process which fully reflects the centre's activities as part of their quality management system	To be monitored in the course of the next inspection.
Licence Displayed The centre's licence was not displayed at the time of the inspection. This is a breach of standard licence condition A.13.4.	No action required – the PR has confirmed that the licence is now on display in the patient waiting room.	
Traceability Details of the pot used to collect semen for therapeutic use is not currently recorded. S.7.3.	The centre should review their traceability procedure to ensure that the sperm pot is included in the record of materials and equipment used in the processing of gametes for therapeutic use.	This was implemented by the Centre with immediate effect on the day of inspection.

Non-Compliance

Area for improvement	Action required	Time scale
The centre does not have a validated staff signature list. G.13.2.2	The PR should consider the recommendation that there should be a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures.	This has been actioned by the centre since inspection.
Witnessing - timed Witnessing records do not include the time at which the witnessing of a sample preparation takes place G.13.2.1(b)	The centre should review their witnessing procedure to ensure that the time at which each movement of gametes in the preparation process is witnessed. Centre staff confirmed that his would be corrected with immediate effect on the day of inspection.	This was implemented by the centre with immediate effect on the day of inspection.
Witnessing training The centre does not currently conduct formal witnessing training and assessment of staff before staff participate in this activity. G.13.4.1 G13.6.1	The centre should ensure that there is a mechanism is place for the training of new staff and the refresher training of other staff as required to ensure that the principles of the witnessing procedures are fully understood and that the centre-specific protocols are followed.	September 09

Recommendations

Area for improvement	Action required	Time scale
Witnessing procedures have not been audited G.13.3.4	The centre should ensure that an audit of witnessing procedures conducted is included within the centre's quality management system audit.	To be monitored in the course of the next inspection
The witnessing procedure has not been risk assessed, G.13.3.1	Following the modification of the risk assessment procedure the centre should perform a risk assessment or at any other time when a change is made to the documented procedure.	To be monitored in the course of the next inspection.

Changes/ improvements since last inspection

Recommendations	Action Taken
Third Party Agreements were to be formulated and agreed with the appropriate parties.	Third Party Agreements formulated and agreed with all relevant parties.
The centre's quality manual required further development.	The Quality Manual has been developed to a good standard.
The centre should develop and agree a quality policy.	The centre's quality policy has been agreed and was available to see.
Risk assessments reflecting the centre's activities, equipment and personnel were to be conducted.	A comprehensive schedule of risk assessment has been conducted and was available to be seen.
The centre was to implement effective document control	An effective document control process was seen to be in place on inspection.
The receipt and witnessing of sample preparation did not incorporate all witnessing steps advises as per guidance.	The receipt and witnessing process has been reviewed by the centre and practice changed.
Air quality is to be established in the andrology semen preparation area.	A class II cabinet has been installed and air quality has been assessed using both particle and micro biological assessment and was found to be compliant with the Code of Practice and with the HFE Act
The centre should ensure that all material in contact with gametes used in treatment should be traceable.	Practice has been reviewed and a traceability system instigated.
A programme of audit was to be established	Patient satisfaction and clinical outcome audits have been conducted.

Additional licence conditions and actions taken by centre since last inspection

No licence conditions in place

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 centre's activities are lead by the PR who is supported by a small clinical and administrative team. The andrology service is lead by the Chief Medical Scientist for the Trust who has overall responsibility for the pathology service with whom the centre has a third party agreement.

In the opinion of the executive, evidence drawn from the inspection demonstrates that the PR provides the required leadership and management skills to fulfil his responsibilities.

During the inspection the centre appeared to be operationally well organised. All pre-inspection material was submitted to the HFEA complete and on time. All members of staff were present for the inspection and provided all the information, written and verbal, as requested.

An organisational chart was seen to be in place which clearly demonstrated current responsibility and reporting lines. Evidence of regular management communication and review of centre activities was seen in the minutes of management group meetings.

The centre participates in the Trust wide clinical governance agenda and was able to demonstrate effective risk awareness on discussion with staff and in reviewing risk assessments undertaken since the last inspection. Key areas of the centre's activities were seen to have been comprehensively risk assessed since last inspection and were reported via The Trust's electronic risk management system and the pathology department electronic quality management system.

The centre manages incidents and complaints in accordance with the Trust polices. No incidents or complaints have been submitted to the HFEA since the initial licence was granted. Both the centre's incident and complaints logs were viewed. No incidents were reportable to the HFEA and the centre had not received any complaints locally since the last inspection. The centre's incident and complaints standard operating procedures (SOP) were seen to be in place. Information regarding how and to whom a complaint should be made was available in patient areas. When asked staff were aware of the HFEA Alert system but had been unaffected in their practice by resent Alerts.

The PR stated that contingency measures are in place to manage the following eventualities and disruption to service:

- Power 'outage' – the centre is part of the Trust emergency back up generator network
- Significant absence of the PR – there is a Nominal Licensee in place and appropriate clinical cover available
- Significant disruption to clinical service on site –contingency arrangement with the regional fertility centre in Glasgow.
- Patients requiring admission to hospital under emergency conditions are managed in the gynaecology ward, located within the campus of Crosshouse Hospital. Instructions for emergency arrangements (including out of hours) are contained in the patient information leaflets.
- Equipment for use in the resuscitation of a patient who may collapse is available for use in the centre but is located in the adjoining Cardiac Rehabilitation Department on the same floor. This equipment is maintained by this department and was not seen on this inspection.

Details of all third party agreements in place were seen on inspection.

Monthly meetings are held, evidence of this was supplied by means of meeting agendas and consequent minutes. A schedule of meeting dates was also supplied dating from 09/09/08 to 09/09/09. Topics discussed during these meetings included training, staffing levels, risk assessments, andrology laboratory air quality and the quality manual. It was noted from the minutes that a representative from the laboratory (with whom the centre has a third party agreement) attends these meetings, this person said she felt there was effective communication between the centre and laboratory. Information for centre meetings was fed back to other laboratory staff via their own team meetings and meeting minutes.

The finance department of the HFEA report prompt payment of renewal fees to date.

Areas for improvement

The content of third party agreements viewed was variable. In some cases, a third party agreement was represented just by a quality management certificate from the supplier and in other formal agreements not all requirements of standard licence conditions A.5.4 had been adhered to; in particular not all agreements included:

- the name of the responsible persons
- review period for the third party
- an outline of the responsibilities of the third party and licensed centre.

Areas for consideration
The centre adopts the Trust incident reporting procedures but these do not reference the timeframes required for reporting incidents to the HFEA. The centre may wish to consider amending the Trust incident reporting SOP locally to reflect the reporting time frame requirements of the HFEA in addition to that required by the Trust.
Executive recommendations for Licence Committee
The PR should review the content of third party agreements against the requirements of standard licence condition A.5.4 and CoP G.2.1.2 and update the agreements accordingly.
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered

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
The results of an internal audit conducted by the centre were available to the executive on inspection. The audit for the period April 08 to March 09 concluded that 81 cycles of IUI had been conducted giving and average of 7.75 cycles per month, with an overall success rate of 8.64%.
Areas of firm compliance
Since last inspection, the PR and staff within the unit have demonstrated commitment to the establishment and maintenance of a Quality Management System (QMS). The fertility nurse specialist who also has the role of quality manager leads the development of the QMS. The centre's commitment to quality is outlined in a policy within the quality manual and incorporates all elements required by the 7th Code of Practice. In compliance with HFEA Standards, the quality manual clearly outlines: (a) a description of the centre, including its legal identity, and the scope of the services provided, (b) a quality policy (c) an organisational chart and a definition of the centre's place in any parent organisation, (d) an outline of the processes and documentation established for the quality management system. A list of measurable quality objectives for the year 2008/09 were seen and were said by staff to be under review for the period 2009/10, following the annual formal centre management review which was held on 03/06/09, evidence of which was seen for both 2008 and 2009. The centre to date has conducted a limited number of internal audits, namely clinical success rates and patient satisfaction. An analysis of the findings, together with the raw data and an action plan / evaluation of the actions for each audit was provided for the inspection team to review.

Documents received during the course of inspection proved compliant with HFEA Standards in that they are uniquely identified, the edition and operative date, the total number of pages, authority for issue and author identification.
Areas for improvement
The review of the centre's documented quality objectives for the period 09/10 is outstanding. The centre's internal audit programme is limited and does not fully reflect all the aspects of the centre's activities.
Areas for consideration
Executive recommendations for Licence Committee
The centre should complete the review of current documented quality objectives to meet the needs and requirements of the users that are measurable and consistent with the quality policy. S.4.2.4 The centre should formulate an audit schedule of the activities for which a licence is sought. The audits should be conducted at least every two years in an independent manner against compliance with the approved protocols and the regulatory requirements. All findings and corrective actions must be documented in accordance with standard licence condition A.10.32
Evaluation
Some improvement 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

Brief description of premises
The licensed premises are located on the ground floor of the MacDonald Suite, a stand alone building on the campus of Crosshouse Hospital.
Areas of firm compliance
The premises and facilities available appear to be suitable for the activities for which the centre is licensed. The clinical facilities appeared to provide for the privacy, dignity and comfort of (i) those seeking treatment and (ii) those undergoing examination and treatment and (iii) providing semen samples for therapeutic use. The centre have made positive attempts to improve the level of service user privacy when attending the reception desk following user satisfaction feedback documented in the centre's survey results. The small semenology laboratory is located adjacent to the treatment room and appears to be appropriately equipped for current licensed treatment. Staff state that the room is usually locked when not in use. A class II workstation is in use for semen preparation. Air quality of the environment in which semen is prepared for therapeutic use is now monitored quarterly using settle plates and a particle counter. The most recent results of which were available, background air was measured as Grade D and Grade A within the cabinet. Scheduled maintenance logs and portable appliance testing (PAT) for clinical equipment seen was in date. The maintenance agreements for laboratory equipment in the centre were not available as they are currently under review by the Pathology Department. Staff rest facilities within the centre are limited but a full range of staff catering and changing facilities are available within the main body of the hospital.

Patient treatment records were seen to be stored securely in designated locked cabinets in an area of the treatment room to which access is restricted to authorised personnel.
Areas for improvement
None noted
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
No improvement required
Evaluation
No improvement required
Areas not covered on this inspection
Formal counselling is no longer available at this centre. Gametes are not stored at this centre.

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
Information for service users submitted prior to inspection and seen on the day was found to be current, clearly presented and relevant to the treatments for which the centre is licensed. It was noted that an information checklist is used to ensure patients have received and understood all the information they require to give valid consent. The executive conducted an audit of five randomly selected patient treatment records. All records were seen to be in good order with no omissions or discrepancies and included an information checklist. The patient information reviewed broadly complied with CoP guidance on informed consent (CoP G.5.2), information for those seeking fertility treatment (CoP G.5.3.1) and risks of multiple births associated with ovulation induction (CoP G.5.3.2). In instances where the inspection team could not locate the required information, the PR was able to describe a system for informing patients verbally of this information. This centre is not currently required to make formal consideration of welfare of the child prior to treatment, however the changes in this requirement from October 2009 were discussed on inspection. There is a Trust policy in place for the controlled access to health records.
Areas for improvement
The registry department of the HFEA report no submission of treatment data to date. This is in breach of General Directions D.2008/6.
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should ensure that treatment data is submitted to the HFEA in a timely manner in accordance with General Directions D.2008/6
Evaluation
Some improvement required

Areas not covered on this inspection
Welfare of the child

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
- Laboratory practice
  - Procurement, distribution and receipt of gametes
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Witnessing

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	2
Non NMC registered clinical staff	0
HPC registered scientists (by third party agreement)	0
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	1
Counsellors	0

Summary of laboratory audit
There are no stored gametes at this centre.
Summary of spot check of stored material
There are no stored gametes at this centre.
Areas of firm compliance
The two Nursing and Midwifery Council (NMC) registered nurses working within the centre have may years experience of fertility services. Following consultation with a member of the medical team, as part of the patient pathway, patients and their partners attend an information and treatment planning appointment with a member of the nursing team. The senior nurse is also responsible for ultrasound scanning of patients in treatment. Both nurses perform IUI procedures. On discussion with the scientific inspector, laboratory staff were able to demonstrate that they were appropriately qualified and skilled to perform the procurement, distribution and receipt of gametes. Staff from this department who provided a service to the centre participate in the National External Quality Assurance Service (NEQAS) for andrology. Evidence of participation during March and June 2009 were seen, the results of which were within acceptable range. Two of the laboratory staff are members of the British Andrology Association (ABA) and all laboratory staff members participate in clinical professional development (CPD), some of which may be related to andrology. Staff also stated that they participate in an annual Professional Development and Appraisal

process in accordance with Trust policy. Evidence for this was not seen.

Crosshouse Hospital Pathology Department, with whom the centre has a third party agreement to provide diagnostic and therapeutic andrology services, has Clinical Pathology Association (CPA) accreditation.

The centre was able to demonstrate good documentation for the tracking of materials and equipment used in the processing of gametes with one exception documented below.

Areas for improvement

Whilst it is acknowledged that staff are competent to perform designated tasks, the centre does not have procedures in place for the assessment of staff competence.

Staff interviewed stated that access to appropriate CPD and training to support experiential learning in areas such as ultrasound scanning, for both initial and update training has traditionally been difficult to access. This is said to be partly due to the location of the centre, difficulty in releasing key staff to attend and funding issues. Review of staff training logs supported this finding.

It was noted that the centre were not recording information for traceability relating to the pots used for collection of semen for therapeutic use. This was discussed on inspection and it was agreed would be added to the record.

The centre does not have a validated staff signature list.

Areas for consideration

The PR should satisfy himself that under the terms of the third party agreement held with the Pathology Department that staff performing semenology at the centre have sufficient andrology related clinical professional development to maintain current, good clinical practice and have had their competence in such areas assessed.

The centre's procedure for the witnessing of samples in preparation was discussed and was found to be largely compliant with 7th CoP guidance.. It was however agreed that the time at which the witnessing steps were observed during the preparation process would be added to the record with immediate effect.

Executive recommendations for Licence Committee

The centre should establish documented procedures for staff management that ensure that all staff have competence assessment. A.10.11

The competency of the personnel must be evaluated at appropriate intervals specified in the quality system. The PR must ensure and document that each individual: has demonstrated confidence in the performance of their designed tasks,.S.6.2.2 (c)

A continuing education and professional education programme should be available to staff at all levels. S.6.2.11

Staff should be given adequate opportunity to access appropriate training and professional development which is updated as required when procedures change or scientific knowledge

develops. S.6.2.7
Evaluation
Some improvement required
Areas not covered on this inspection
Donors are not recruited at this centre No gametes or embryos are stored and no embryos transferred at this centre.

Report compiled by:

Name Gillian Walsh

Designation Inspector

Date 25 June 2009

Appendix A: Centre staff interviewed

The Person Responsible, the Nominal Licensee two specialist fertility nurses and the centre's directorate manager.

Appendix B: Licence history for previous 3 years

Licence award

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Appendix C: Response of Person Responsible to the inspection report

Centre Number..... 0287.

Name of PR..... CLIVE BAIRD.

Date of Inspection..... 17th June 2009.

Date of Response..... 23RD July 2009.

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

Signed..... Clive H. Baird.

Name..... CLIVE H. BAIRD

Date..... 23RD July 2009.

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

NO CORRECTIONS.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

NO FURTHER COMMENTS / INFORMATION.

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

AM HAPPY TO COMPLY WITH RECOMMENDATIONS.

HFEA Executive Licensing Panel Meeting
14th October 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Crosshouse Hospital (0287), Licence renewal

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Trish Davies, Director of Compliance	Committee Secretary: Joanne McAlpine

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 (36 pages)
- 1 item was tabled for this item – an updated email from the inspectorate on behalf of the centre

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 9th September 2009
- Indicative sanctions guidance approved by the Authority on 18th March 2009
- Licence application and any relevant documentation

1. The Panel noted that this centre was first licensed by the HFEA in 2007 and had made significant improvements since the last inspection.

2. The Panel noted that the licence renewal inspection of this centre took place on the 17 June 2009, and further improvement was required in the following areas;
    - Submission for treatment data to the HFEA in accordance with general directions D.2008/6
    - Witnessing procedures and training for all staff G.13.4.1 and G.13.6.1
    - The competency of personnel must be evaluated at appropriate intervals specified in the Quality Management System, and has demonstrated confidence in their designated tasks S.6.2.2

3. The Panel noted that this IUI centre is a relatively small unit that has carried out 42 IUI treatments in the time period from 7 July 2008 to 31 December 2008.

4. The Panel noted and agreed to accept the tabled email that had been put before them as it appeared to update the Panel both from the centre's and the executive's perspectives. The information reflected that the Centre has addressed or is in the process of addressing the following areas:
    - Timely submission of licensed activity data to HFEA
    - Formulation and execution of an internal audit schedule which reflects the centre's activities
    - The availability of professional development and update training and the assessment of staff competency
    - Access to appropriate clinical professional development for staff
    - Revision of existing third party agreements.
    - Revision of witnessing procedures to include the time witnessing stages are observed
    - Validation of laboratory equipment, practices and processes

5. The Panel noted the response from the Person Responsible and were assured by the very positive approach to comply with the inspectors recommendations.

6. The Panel referred to section 16 of the Act for the granting a renewal of a licence subsection 4, and agreed that they had sufficient information in which to make a decision.

The Panel's Decision

7. The Panel noted that the PR had completed the PR Entry Programme and 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 HFEA Act 1990 (as amended). On the basis of the

information provided, the Committee agreed that it was satisfied of the suitability of the Person Responsible and the premises.

8. The Panel 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.

9. The Panel considered whether to impose an additional condition on the licence requiring compliance with the recommendations within the timescales specified. The Panel concluded that it would not impose an additional condition on the basis that the relevant recommendations had been addressed or were going to be addressed within the timescales specified. The Panel however did agree that the inspectorate should chase the centre for any outstanding treatment data that has not been submitted up to July 2009.

10. The Panel decided in accordance with the recommendation from the Inspectorate to renew the centre's licence for a period of 4 years with no additional conditions.

Signed..... Date 22 October 2009.
Peter Thompson (Chair)