Inspection Report

Date of Inspection: 27 January 2011
Purpose of inspection: Renewal of Treatment Licence
Length of inspection: 6.5 hours
Inspectors: Miss Allison Cummings, Mrs Sara Parlett and Mr David Gomez (observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 12 January 2010 and 29 April 2011.

Date of Executive Licensing Panel: 29 April 2011

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. 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 Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	The Whittington Hospital Fertility Unit
Centre number	0258
Licence number	E0258/2/b
Centre address	Jenner Building Whittington Hospital Magdala Avenue London N19 5NF
Person Responsible	Mr Gidon Lieberman
Licence Holder	n/a
Date licence issued	01/07/2009
Licence expiry date	30/06/2011
Additional conditions applied to this licence	none

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The Whittington Hospital Fertility Unit was first licensed by the HFEA for the provision of Intra Uterine Insemination (IUI) with partner sperm in 2007. The unit t is located within the gynaecology outpatients department in the main hospital building. The licensed premises also include a dedicated laboratory for processing sperm samples, two consulting rooms and a treatment room.

The centre provides approximately 300 cycles of NHS funded IUI each year to patients from the local area.

The Person Responsible (PR) is a consultant Gynaecologist and Obstetrician, advising on and overseeing medical activities at all times. He is registered with the General Medical Council and has also been on the specialist register for Obstetrics and gynaecology (Reproductive Medicine) since January 2005. He successfully completed the Person Responsible Entry Programme in 2007.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 Jan – 31 December 2010
IUI with partner sperm	318

Clinical Pregnancy Rates
The centre reported an 8.2% clinical pregnancy rate for 2010 for IUI with partner sperm.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have 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 is suitable and has discharged his duties under section 17 of the HF&E Act 1990 (as amended);
- the premises are suitable;
- the practices are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement including two major areas of non-compliance and four other areas of non-compliance.

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

- when a procedure that requires witnessing takes place, make a record in the patient notes stating the time this is done;
- all equipment with critical measuring function must be calibrated against a traceable standard if available;
- for each patient maintain a record of how, and by whom, the patient has been reliably identified;
- arrange payment of the annual fee within the timescale specified in Directions or in writing.

The PR has given a commitment to fully implement the following recommendations relating to the two major areas of non-compliance:

- establish quality indicators for assessing the welfare of the child, consent taking and information provision. Additionally, audit these activities against compliance with the approved protocols, the regulatory requirements and quality indicators;
- establish written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos.

Recommendation to the Executive Licensing Panel

The inspection team 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 conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further improvement is required in only a two areas of practice.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately.

Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

There are measures in place to ensure that patients receive treatment using the correct gametes. As recorded in written procedures, patient records and audit reports, there are always two staff members who double check the identification of gametes and the patient to whom they relate at all critical points of the clinical and laboratory process. Furthermore, staff confirmed that one sample is processed at a time, further limiting the chances of a mix-up.

The centre has a documented Standard Operating Procedure (SOP) describing a comprehensive witnessing procedure to be followed at all critical stages from the receipt of the semen sample to insemination. Staff demonstrated a clear understanding of the requirements of witnessing procedures and these accorded with the SOP. The competence of relevant staff members to carry out sperm preparation and IUI procedures had also been documented.

The centre has set a quality indicator for 2009/10 of auditing 100% of patient files. The last witnessing audit report was reviewed at inspection. The audit included both the laboratory and clinical witnessing practice. The audit report recorded that there was a 100% compliance with the witnessing requirements and that no corrective actions were required.

Inspectors saw that there is a record kept of the procedure, date, signature of the person doing the procedure, and the signature of the witness. Furthermore, there is a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.

What the centre could do better.

The time that procedures are witnessed is not recorded (CoP Guidance Note 18.7(b)).

Patient selection criteria and laboratory tests (Guidance Note 11)

What the centre does well.

The overseeing scientist explained that the microbiology department within the hospital is responsible for the diagnostic and investigative testing of patients. He confirmed that this laboratory is accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd. As the centre's policy is to screen patients prior to treatment, the overseeing scientist was also able to provide evidence that this testing takes place in a CPA accredited laboratory.

What the centre could do better.

Nothing noted at the time of inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

Good clinical practice is achieved through an effective quality management system; procedures to trace gametes and materials which have the potential to affect their quality; validation of critical processes and equipment; appropriate premises, equipment and management of incidents:

Quality management system
The quality management system is used to continually improve the quality and effectiveness of the service it provides in accordance with good practice. Minutes of the half yearly quality review meeting demonstrated that there is a forum to discuss and monitor quality issues, including clinical outcomes for patients. The quality system includes a quality manual, standard operating procedures, and reference and training materials for staff.

The inspection team considered that the reference and training materials for staff were particularly well developed. They were established in the form of a training and awareness programme, containing lectures and presentations for staff to reference. It also included lectures and presentations developed by the PR in his role as a teacher for the British Fertility Society. The quality manager showed examples of records demonstrating staff had signed off to say they had completed the programme. He explained that this form of training gave staff an opportunity to identify training needs other than standard training

(that is, for continuous professional development). He said that he aimed to deliver education on site so that all staff can achieve a high level of knowledge and skills.

Traceability
Staff record information about all media, consumables and equipment that come into contact with gametes, from procurement to use in treatment. There is a procedure to ensure this information will be kept for 30 years. Inspectors were presented with written procedures, patient notes, a log book, records of training, quality indicators and audits which demonstrated their compliance with traceability requirements.

Validation
Validation of critical processes (sperm preparation and the insemination procedure) has been performed. The overseeing scientist showed inspectors the written procedures for validation, which described how these have been based on published studies and other comparators. Further measures, including 'process observations' of some nursing staff, have been carried out by the overseeing scientist. These steps further ensure that gametes are not rendered clinically ineffective or harmful to the recipient.

Equipment and materials
The overseeing scientist provided written evidence that critical equipment had been validated and is regularly serviced and monitored. Equipment manuals are kept and inspectors saw that there are written procedures for responding to equipment failures.

The quality manager said that all medical devices are CE marked. Samples of these were seen by inspectors.

The fertility nurse specialist said that the scanner is serviced and tested for electrical safety on a rolling programme managed by the Trust. She also confirmed that equipment is cleaned routinely prior to each procedure. Records showed that there is regular cleaning of the laboratory.

Premises
Inspectors observed that the premises are suitable for the treatment services offered and that all licensed activities take place on the licensed premises. They appeared clean and well organised and weekly cleaning records showed a commitment to general cleanliness and infection control.

An external company monitors the air quality on an annual basis. The most recent report from December 2010 indicated that the air quality in the laboratory exceeded HFEA requirements with grade A in the hood and grade D background air.

Adverse incidents
There are documented procedures for reporting serious adverse events and reactions that may occur. Staff articulated a good understanding of adverse events and reactions, and procedures for reporting these to the HFEA and the Trust.

Third party agreements
Inspectors reviewed three of the five agreements that are in place with providers of goods that influence the quality of gametes. These contained the necessary information, meeting HFEA requirements.

What the centre could do better.

Quality management system
The quality manager has established quality indicators for all activities authorised by the centre's licence except for the following: welfare of the child (WoC) assessment, consent taking and information provision (Licence Condition T35). Furthermore, these activities have not been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years (Schedule 3A (10) 2006/86/EC, Appendix 1 F and Licence Condition T36).

Equipment and materials
The refrigerator containing reagents for sperm preparation procedures is monitored. However, the thermometer has not been calibrated against a traceable standard, potentially compromising the accuracy of readings (Licence Condition T24).

Third party agreements
Although there are agreements in place for the goods that influence the quality of gametes, there were no agreements in place for service providers who monitor air quality and service critical equipment (Licence Condition T111).

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

The Person Responsible
The PR has carried out his duties in accordance with Section 17 (1) (a) of the HFE Act 1990 (as amended) as documented throughout the body of this report.

Staff
The PR has, in post, suitably qualified staff to carry out the services offered. Nursing staff are registered with the Nursing and Midwifery Council. The overseeing scientist is registered with the Health Professions Council. He was able to demonstrate his participation in the UK National External Quality Assessment Service scheme, helping to ensure clinical laboratory test results are accurate, reliable and comparable.

Furthermore, the organisation chart clearly defines accountability and reporting relationships.

The overseeing scientist works at the centre two mornings per week. Staff confirmed that he is accessible by telephone at other times. He has trained and assessed the fertility nurse specialists to prepare sperm for insemination procedures so that the service can continue during his absence. The training and competence assessments take place annually and this has been clearly documented. Records for other assessments were shown to inspectors, except for scanning as the records were held in the main imaging department. These demonstrated that nursing staff were competent to take provide

patients with appropriate information, assess the welfare of the unborn child, obtain patient consent, witness procedures, and document required data for traceability purposes.

With regard to workforce requirements, the lead fertility nurse specialist said that these had been risk assessed and deemed adequate since the appointment of a second fertility nurse specialist in April 2010. This has significantly reduced waiting times for patients. Previously the waiting time for an initial appointment was four months. There is currently no waiting period.

What the centre could do better.

Nothing noted at the time of inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Staff provided verbal and written evidence that before providing treatment services, account is taken of the welfare of any child who may be born as a result of the treatment and of any other child who may be affected by the birth. The centre has written procedures to guide staff through this assessment. The centre has a patient information leaflet describing in detail the Welfare of the Child assessment. Inspectors audited five records which showed that all patients and their partners had completed the assessment form prior to being offered treatment.

The lead fertility nurse specialist described robust procedures for escalating concerns that have arisen as a result of the WoC assessment process. She explained that in two instances in the last year, further information was sought from the patients and this discussion was documented in patient notes. The weekly staff meeting is the forum used to escalate and discuss whether it would be appropriate for a couple to be offered treatment, following the receipt of further information from other health professionals in the community. Minutes of these discussions were shown to inspectors. The lead fertility nurse said that the team are exploring the option of using the Trust's ethics committee for further cases. She articulated the need for achieving a balance of treating people fairly and referred to the hospital policy which she said all staff have a duty to adhere to. She added that the team have to be practical and therefore they also refer to NICE guidelines for consideration of cases.

For information about quality indicators and audits, please see section 'Good Clinical Practice'.

What the centre could do better.

Nothing noted at the time of inspection.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plan (Guidance Note 4)

What the centre does well.

Treating patients fairly
Staff provided evidence that an effective Trust Equal Opportunities policy is in place and that they all they receive mandatory training in how the policy should be applied in practice. In discussion and in documentation seen, staff were able to demonstrate that patients are treated fairly and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances.

Complaints
The centre has a process to investigate and learn from patient complaints and this was clearly visible in the patient waiting room. Staff described the centre's procedure, demonstrating a clear understanding of the proper processes to follow to resolve patient complaints.

The centre's policy states that written complaints should be logged. However, no written complaints have been received and this was also confirmed in a recent email from the Trust's Patient Advice and Liaison Service. Inspectors saw that the complaints log is empty but is held on a shared drive so that staff can access it if they need to.

Provision of a costed treatment plan
As the service is funded by the NHS, this topic was not reviewed on inspection.

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)

What the centre does well.

The PR submitted a suite of patient information prior to the inspection, covering the majority of the requirements of the Code of Practice. All information as stipulated in Licence Condition T58 is provided to patients in writing. Inspectors saw that a checklist present at the front of patient notes was used as a reminder to ensure that all relevant written information had been given. Staff said that the only information not provided in writing related to the policy on selecting patients and the expected waiting time for treatment. They explained that this was discussed verbally on initial contact with patients. Written procedures for providing information to patients were shown to inspectors. Inspectors met with a patient to discuss her experiences at the centre. She said that all staff made lots of time for her and her partner to discuss the various aspects of treatment, for example, the nature of treatment, outcomes and treatment risks. Subsequently, she considered that she and her partner were well informed prior to giving their consent to treatment.

What the centre could do better.

Nothing noted at the time of inspection.

Consent

- Consent to treatment (Guidance Note 5)

What the centre does well.

Written consent is obtained from patients and partners before any form of treatment is provided. Evidence of this was seen in the five patient files reviewed at inspection. The centre has set a quality indicator of 100% compliance for 2009/10 for recording the consent to treatment on the correct form. The centre's audit, reviewed at inspection, demonstrated 100% compliance with the centre's quality indicator.

What the centre could do better.

Nothing noted at the time of inspection.

3. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
  - maintaining up-to-date awareness and understanding of legal obligations
  - responding promptly to requests for information and documents from the HFEA
  - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare.

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patients records reviewed at the time of inspection were seen to be clear, legible and well organised. Each record reviewed was seen to include: patient's first name, surname, date of birth, age and sex. The WoC assessment; relevant documented consents and clinical and laboratory data and the results of tests carried out are also kept in patient records. This data is kept in a separate record from main hospital notes and these are kept in a locked cabinet in the treatment room.

Inspectors were informed that the patient's medical history and justification for the use of gametes (based on their medical history together with therapeutic indications) is recorded in hospital notes kept in the main records department within the hospital.

There is a document control procedure which ensures that only current versions of documents are in use. Centre documents are reviewed annually.

What the centre could do better.

Staff explained that it is standard practice to verify patient and partner identity by requesting photographic evidence at the time they consent to treatment. However, staff explained that they could not demonstrate to inspectors that this check is carried out as it was not recorded in patient notes (CoP Guidance 5.11).

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

The PR provided all information as required by the application process prior to inspection. All members of staff cooperated fully with the inspection team and further information requested at the time of inspection was provided in a timely manner.

What the centre could do better. The HFEA's finance department reported that the centre was invoiced for its annual fee on 29 October 2010 but this was not paid within 28 days. The fee remains unpaid. The PR explained that this was a Trust finance department issue and that although he had reminded them numerous times, it remains unpaid. Chair's Letter CH 10(02) regards this as a breach of Licence Condition T9 (d).

4. Changes / improvements since the previous inspection on 12 January 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
The units audit demonstrated that 16% of double witnessing signatures are missing from patient documentation. Licence Condition T71	The PR should ensure that witnessing is carried out by two members of staff contemporaneously with the procedure and that both provide documented signatures.	The PR arranged for staff to perform an audit of all procedures which took place in 2010. The results informed inspectors that all records were 100% compliant with written procedures and Licence Condition T71. A further five sets of patient notes were audited by inspectors: all witnessing procedures reviewed had been carried out by two members of staff and signed accordingly. The quality manager said that the appointment of a fertility nurse specialist in April 2010 ensured that it is possible for all procedures to be witnessed. No further action is required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Quality indicators have not been established for the following critical activities: WoC assessment, consent taking and information provision (Licence Condition T35). Furthermore, these activities have not been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years (Schedule 3A (10) 2006/86/EC, Appendix 1 F and Licence Condition T36).	Establish quality indicators for: • welfare of the child; • consent taking; • information provision. Audit the above activities against compliance with the approved protocols, the regulatory requirements and quality indicators. 27 April 2011	accept suggestions in development and time scale	Satisfactory response. Further action required and this will be monitored via the compliance cycle.

There are no third party agreements in place with service providers who monitor air quality and critical equipment. These services have the potential to influence the quality of gametes (Licence Condition T111).	Establish written agreements with all third parties who provide goods or services that influence the quality and safety of gametes and embryos. 27 July 2011	These have been requested from third parties who provide/ service equipment.	Satisfactory response. Further action required and this will be monitored via the compliance cycle.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The time that procedures are witnessed is not documented (CoP Guidance 18.7 (b)).	When a procedure that requires witnessing takes place, a record should be made in the patient notes of the time this is done. 27 April 2011	added to witnessing document	No further action required.
The thermometer for monitoring the fridge has not been calibrated, potentially compromising the accuracy of readings (Licence Condition T24).	All equipment with critical measuring function must be calibrated against a traceable standard if available. 27 April 2011	A new thermometer has been purchased.	No further action required.
Staff could not demonstrate	For each patient maintain a record of how, and by whom,	addition of photo ID clarification for both partners to	No further action required.

that the identities of patients (and their partners) were checked against identifying information in the medical records. (CoP Guidance Note 5.11)	the patient has been reliably identified. 27 February 2011	IUI checklist	
The PR has not arranged payment of the annual EUTCD fee for which he was invoiced 29 October 2010. (Licence Condition T9 (d)).	Arrange payment of the fee before 27 April 2011. In future, make arrangements so that payment of fees for treatment cycles is no later than 28 days from the date on the Authority's invoice.	Issue has been taken up with trust management.	No further action required. The Authority received payment 3 February 2011.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting
8 April 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0258 (The Whittington Hospital Fertility Unit) – Renewal Inspection Report (Treatment only)

Members of the Panel: Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Danielle Hamm, Policy Manager	Committee Secretary: Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is an IUI centre and was first licensed by the HFEA in 2007.

2. The Panel noted that the licence renewal inspection took place in January this year and lasted six and half hours.

3. The Panel noted that the centre provides approximately 300 cycles of NHS funded IUI each year to patients from the local area.

4. The Panel noted that the centre has reported an 8.2% clinical pregnancy rate for 2010 for IUI with partner sperm.

5. The Panel noted that at the time of the inspection two major and four other areas of non-compliance were identified.

6. Since the inspection, the Person Responsible (PR) has confirmed that the recommendations relating to witnessing, maintaining of patient records and arranging payment of the annual fee within the timescale specified have now been fully implemented.

7. The Panel noted that the PR has given a commitment to fully implement the recommendations concerning the two major areas of non-compliance:

    - Establish quality indicators for assessing the welfare of the child, consent taking and information provision. Additionally, audit these activities against compliance with the approved protocols, the regulatory requirements and quality indicators
    - Establish written agreements with all third parties which provide goods or services that influence the quality and safety of gametes and embryos.

8. The Panel confined its consideration to the evidence before it.

9. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a period of four years without any additional conditions.

10. The Panel noted that the centre has made considerable improvements since the last interim inspection in 2010, in particular in relation to witnessing.

Decision

11. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and that the application contained the supporting information required by General Direction 0008.

12. The Panel was satisfied that the character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

13. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

14. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

15. The Panel noted that no application was being made to use embryos for training purposes or to store gametes or embryos.

16. The Panel had regard to 'Guidance on periods for which new or renewed licenses can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3. On the basis of the PR's responses to the inspection and the action taken on the major non-compliances, the Panel agreed that it had no concerns.

17. The Panel therefore agreed to renew the centre's licence for a period of four years with no additional conditions.

18. The Panel endorsed the recommendations in the inspection report for further action by the Person Responsible, and noted the PR's commitment to comply with these recommendations.

Signed: Date: 19 April 2011

Mark Bennett (Chair)