Inspection Report

Date of Inspection: 19 January 2012
Purpose of inspection: Renewal of Treatment Licence
Length of inspection: 7 hours
Inspectors Parvez Qureshi
Vicki Lamb

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 7 January 2010 and 6 April 2012.

Date of Executive Licensing Panel: 20 April 2012

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	Assisted Conception Unit, Leigh Infirmary
Centre number	0278
Licence number	E0278-2-c
Centre address	The Avenue, Leigh, Lancashire, WN7 1HS.
Person Responsible	Mr Phillip Harris
Licence Holder	--
Date licence issued	01 July 2008
Licence expiry date	30 June 2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The Assisted Conception Unit, Leigh Infirmary is part of the Obstetric and Gynaecological Directorate of Wrightington, Wigan and Leigh NHS Trust. The unit was first granted a licence in 2007 for basic partner treatment services. The current licence was granted on 1 July 2008 and will expire on 30 June 2012. A fee paying service is available to those patients who do not fulfil the National Health Service (NHS) criteria for Intrauterine Insemination (IUI) treatment.

The unit provides in vitro fertilisation (IVF) satellite services for CARE Manchester (centre 0185) and St Mary's Hospital NHS Trust (centre 0067) and these were also reviewed during this inspection. Patients who require IVF treatment are treated up to the point of egg collection and then referred to either centre 0185 or 0067 for completion of their treatment.

Since the last inspection in January 2010 no major changes have been made to the premises.

The Person Responsible (PR) has academic qualifications and more than two years of practical experience, as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). The PR has successfully completed the HFEA PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period I January 2010 – 31 December 2010*
Intra uterine insemination (IUI)	135

Other licensable activities	Not applicable

Outcomes*
For the year 2010 the centre reported 135 cycles of partner insemination with 16 pregnancies. This equates to a 12% pregnancy rate.

*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.

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, with the exception of the areas of non-compliance identified in this report, discharged his duty 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 one major area of non-compliance and one other area of non-compliance or area of poor practice.

Since the inspection visit on 19 January 2012 the PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that quality indicators (QIs) or objectives relevant to all activities authorised by this licence are established.

Other areas of practice that require improvement:

- The PR should ensure that the identification of persons responsible for managing the arrangement between the centre and the third party, and review dates are included in any third party agreement.

The inspection team recommend the renewal of the centre's licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

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.

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

What the centre does well.

Witnessing – Guidance Note 18

There is a standard operating procedure (SOP) in place for the process to be followed when carrying out witnessing (Standard Licence Condition (SLC) T33(b)). A review of the witnessing SOP and discussions with laboratory staff demonstrated that processes are in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. The scientific inspector noted in patients' medical records that the witnessing checks are carried out and documented appropriately at the time the procedure takes place (SLC T71).

Ten sets of patients' notes were audited for witnessing during the inspection. All were found to contain a record of all required witnessing checks which included the names, status and signatures of staff performing the checks (Code of Practice (CoP) Guidance 18.8).

An annual audit of witnessing practice is undertaken by the centre staff and evidence of this for 2011 was reviewed during the inspection (SLC T36).

Staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing. The centre's witnessing SOP outlines who can witness and there is a formal training programme in place for witnesses who must have refresher training annually (SLC T15 (a)).

What the centre could do better.

The centre has not established quality indicators (QIs) relevant to witnessing (T35).

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Discussion with staff and an audit of IUI and IVF patients' files during the inspection found justification for treatment, medical history and laboratory test results for all patients having treatment at the centre. Evidence was provided by laboratory staff to show diagnostic semen analysis and blood tests for IVF patients are undertaken in a laboratory which has been accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T21).

Counselling: Guidance Note 3
Although not required for IUI patients, counselling is offered to all patients at the start of their treatment. This includes those having IVF treatment. This was evidenced during the review of the centre's patient information and discussion with the centre's counsellors (Act schedule 3, S.3 (1)(a)). An audit of patient records demonstrated that the offer and uptake of counselling is documented.

Evidence of counselling service audits being undertaken and the findings of these audits was seen during the inspection (SLC T36).

Documented evidence of the assessment of their competence to provide counselling was seen for all three counsellors working at the centre (SLC T15 (a)). All counsellors are accredited under the British Infertility Counselling Association (BICA) accreditation scheme.

The centre can refer oncology patients to CARE, Manchester (centre 0185) for specialist counselling, if required.

What the centre could do better.

The centre has not established QIs relevant to counselling (T35).

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.

The quality management system – Guidance Note 23
The centre has a quality management system (QMS) in place but this requires further development (SLC T23). Currently the majority of the QMS is in paper format and is being

transferred over to an electronic format. A process is in place for an on-going review of the performance of the QMS to ensure continuous and systematic improvement.

The QMS consists of a quality manual, SOPs and training and reference manuals, as required by SLC T33. Evidence of audits for consent, welfare of the child (WoC) and witnessing were seen. The findings of the audits and, where required, the corrective actions taken were also seen on inspection (SLC T36).

The centre has a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed during the course of the inspection.

Traceability - (Guidance Note 19)
The centre has a process in place to ensure all gametes are traceable from procurement to patient treatment. All relevant data relating to anything coming into contact with those gametes is traceable. Media batches and the flow hood used are recorded on treatment forms and the centre also maintains a traceability record book for all consumables (SLC T99).

Containers are, at all stages of procurement and processing, labelled with the patient's name, date of birth and a unique laboratory number. The laboratory number is also documented in the patient notes (SLC T101).

The PR reported that the centre has a procedure in place to ensure traceability data is stored for 30 years (SLC T103).

The centre has a SOP which documents the procedures to ensure traceability (SLC T33b).

Evidence of audits for adherence to traceability was seen during the inspection and, where required, corrective actions had been documented and implemented (SLC T36).

Process Validation - (Guidance Note 15)
There are SOPs in place which document all critical procurement and processing procedures (SLC T33b). Laboratory staff provided evidence of validation, of critical procurement and processing procedures which influence the quality and safety of gametes (SLC T72). This validation included reference to the World Health Organisation (WHO) manual.

Equipment and materials - (Guidance Note 26)
Laboratory staff provided documented evidence of the regular cleaning, disinfection, maintenance and regular inspection of equipment in accordance with manufacturer's instructions. Records of servicing of the flow hoods were provided in evidence (SLCs T23 and T26).

Critical equipment has been validated. Documented evidence of equipment validation was seen for a flow hood and a balance (SLC T24).

Laboratory staff reported that instruments or devices used for the procurement of gametes are validated or specifically certified and regularly maintained. Also, where possible the

centre uses CE marked consumables. (SLCs T28, and T30).

Premises – suitability of the premises and air quality (Guidance Note 25)
The activities authorised by the licence are carried out in the premises specified in the licence (SLC T1). All licensed premises are located within the same building. Review of documents submitted for the inspection and discussions with the laboratory staff showed that the critical work area where gametes are processed achieves Grade C air quality, with a background within the laboratory of Grade D air quality. The critical work area is subject to checks on air quality at least every two months (SLC T20).

Adverse incidents - (Guidance Notes 27)
Centre staff demonstrated that there were documented procedures in place for the reporting of serious adverse events and reactions that may occur (SLC T118). These procedures are part of a Trust-wide policy. Since the last inspection in January 2010, no adverse incidents have been reported to the HFEA and no evidence of an adverse incident having occurred was seen during the inspection.

Third party agreements (Guidance Note 24)
A list of all agreements established with third parties who provide goods and services that influence the quality and safety of gametes was seen by the inspection team. This included agreements for the IVF satellite services (SLCs T111 and T115).

Staff reported that no issues have arisen with regard to the ability of third parties to meet the required standards (SLC T112). A review of third party agreements showed that their content was compliant with requirements with the exceptions detailed below (SLC T114).

What the centre could do better.

The quality management system – Guidance Note 23
The centre has not established QIs for all licensed activities (SLC T35).

Traceability - (Guidance Note 19)
The centre has not established QIs relevant to traceability procedures (T35).

Third party agreements (Guidance Note 24)
One satellite third party agreement did not include identification of persons responsible for managing the arrangement between the centre and the third party (SLC T114b). Another third party agreement did not include a review date (SLC T114c).

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible (Guidance Note 1)
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme (PREP number T1125/7).

Staff (Guidance Note 2)
The centre has access to a registered medical practitioner who is able to advise on and oversee the medical activities (SLC T16). The PR was able to confirm that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act Schedule 17 (1) (a)).

The PR reported that the centre has assessed the workforce requirements within the last year and has identified new posts for a quality manager and a consultant. However, the PR confirmed that currently they are operating with a full staff complement and he considered that the number of staff is adequate for the current volume of work being undertaken by the centre (SLC T12).

There is a formal Trust induction training programme in place for all staff; evidence of this was seen in the training records for a member of the nursing and laboratory staff.
The PR confirmed that all staff are competent in their designated tasks. From documentation reviewed at inspection, staff were able to demonstrate evidence of the assessment of their competence to perform designated tasks and participation in relevant professional development by attending training courses and meetings (SLC T15).

Medical, nursing, scientific and counselling staff are appropriately registered with their respective professional bodies (SLC T14).

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.

Welfare of the Child
There is a SOP in place for the process to be followed when carrying out a WoC assessment (SLC T33(b)). The nursing staff reported that prior to any patient being provided with treatment services 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 that birth is considered.
A similar process is in place for those patients having IVF treatment through the satellite arrangements with HFEA licensed centres 0067 and 0185. Evidence of this was seen from a review of IUI and IVF patients' notes which contained WoC forms completed and signed by both partners then reviewed by the clinical staff (SLC T56).

The centre conducted an audit of WoC assessment in July 2011. Where required, corrective actions had been documented and implemented (SLC T36).

What the centre could do better.

The centre has not established QIs relevant to the assessment of WoC (SLC T35).

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)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)

What the centre does well.

Treating patients fairly - (Guidance Note 29)
There are Trust-wide policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner.

Confidentiality and privacy - (Guidance Note 30)
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

All patient records, both for IUI and those having IVF treatment through satellite arrangements, at the centre is kept confidential. Patient records are kept in a secure area and only staff on the centre's licence have access to confidential information. (SLC T43). There is a Trust policy in place to ensure that information is only disclosed in circumstances permitted by law (SLC T43). A SOP for the control of access to health data and records was also seen and was compliant with requirements (SLC T44). The PR reported that as part of the Trust policy all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during the inspection (SLC T15(a)).

Complaints (Guidance Note 28)
There is a complaints procedure in place and staff were able to demonstrate their understanding of how they would resolve a complaint in a timely manner. Since the last inspection in January 2010, no complaints have been made to the HFEA.

Provision of costed treatment plans (Guidance Note 4)
Prior to commencement of treatment, all self-funding patients are provided with a personalised costed treatment plan. The plan provides cost details for the main elements of the proposed treatment. Patients are also informed of any possible changes to the plan, which may be incurred depending on their course of treatment. Staff reported that patients

are given the opportunity to discuss the costed treatment plan with the clinical staff prior to treatment (CoP guidance 4.3).
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.

Information (Guidance Note 4)
Staff reported that all relevant patient information is discussed with patients during the consultation stage and a record of this is kept in the notes. Evidence of this was seen during a review of both IUI and IVF patients' notes.

There is a SOP for the process to be followed when providing information to patients prior to consenting to either IUI or IVF treatment (SLC T33(b)).

Information provided at the time of inspection, including an audit of patient records; an audit of patient information material submitted for the inspection; discussions with staff; patients and the review of the responses from the HFEA patient questionnaire showed that relevant information is provided to patients before treatment is provided.

The centre's website was also reviewed and found to be compliant with Chair's letter CH (11)02 and the Code of Practice (CoP).

The centre has conducted an audit of the provision of information for 2011. Where required, corrective actions have been documented and implemented (SLC T36). Staff were able to provide documented evidence of their competence to provide information for those consenting to treatment (SLC T15(a)).

What the centre could do better.

The centre has not established QIs relevant to the provision of information (SLCs T35).

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

What the centre does well.

There is a SOP in place for the staff to follow when taking consent to treatment (SLC T33b). During the inspection ten sets of patient notes (five each for IUI and IVF) were reviewed and appropriately completed consents seen to be in place (SLC T57). When consents are taken, the identity of the person giving consent is verified and cross-referenced to the NHS number documented within the patients' notes.

The centre has conducted an audit for taking consent and where required, corrective actions have been documented and implemented (SLC T36). A report of the consent audit conducted in June 2011 was made available on inspection. Staff were able to provide documented evidence of their competence to take consent (SLC T15(a)).
What the centre could do better. The centre has not established QIs relevant to taking consent (SLCs T35). The identity of the person giving consent is verified and cross-referenced to their NHS number. However, if a patient's identity is in doubt, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence (CoP 5.10).

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)] • Licensed activities only take place on licensed premises
What the centre does well. From a tour of the licensed premises, review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within premises to which the licence applies. Also all gametes are procured and used in a lawful manner, with appropriate consent.
What the centre could do better. Nothing noted at the time of inspection.

4. 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.

Record keeping and document control: Guidance Note 31
All patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

What the centre could do better.

Nothing noted at the time of inspection.

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 required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner (SLC T9(c) and (f)).

What the centre could do better.

Nothing noted at the time of inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that all information is kept confidential and only disclosed in circumstances permitted by law. The centre has processes in place to ensure that access to the centre's health data and records is kept secure at all times and is only available to centre staff named on the centre's licence or authorised by the Person Responsible (SLCs T43; T44 & T45).

What the centre could do better.

Nothing noted at the time of inspection.

5. Changes / improvements since the previous inspection on 7 January 2010]

Area for improvement	Action required	Action taken as evidenced during this inspection
Witnessing SLC T71	The centre must have witnessing protocols in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place.	There is now an updated witnessing SOP in place. No further action required.
The centre is partially compliant with the establishment of QIs for all the licences activities and other activities carried out in the course of providing treatment services that do not require a licence Licence Conditions T35 and Guidance Note 23	The PR should ensure that the required standards of quality and safety, in the form of QIs for all activities authorized by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established. (Licence Condition T35) Centre management should ensure the quality management system is established and maintained by: (a) appointing a quality manager (c) establishing quality objectives and plans (d) ensuring resources are available to implement and maintain the system (g) conducting management reviews of the system.	(a) The PR reported that quality manager has not been appointed yet but the post is being negotiated. (c) Not all QIs have been established yet. (d) The PR reported that on the appointment of a quality manager the centre will have additional resources to further implement and maintain the QMS. (g) The PR reported that a process is in place for an on-going review of the performance of the QMS to ensure continuous and systematic improvement. Further action required regarding QIs.
Within the last two years the centre has not carried out an audit of licensed activities or activities carried out in the	Trained and competent persons must audit the activities authorised by this licence and other activities	Regular audits are being conducted but not against established QIs.

course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and QIs (Schedule 3A (10) 2006/86/EC, Appendix 1 F and T36). Licence Condition T36	carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and QIs. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.	Further action required.
The centre does not have a Quality Manager Guidance Note 23	Centre management should appoint a Quality Manager who, regardless of other responsibilities, must be responsible for: (a) ensuring that the quality management system is implemented and maintained (b) reporting to centre management on how the quality management system works and how effective it is, and (c) co-ordinating awareness of centre users' needs and requirements. (Guidance Note 23.4)	The PR reported that quality manager has not been appointed yet but the post is being negotiated. No further action 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 identified at the time of this inspection.			

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
The centre is not compliant with the establishment of QIs for all the licences activities and other activities carried out in the course of providing treatment services that do not require a licence SLC T35	The PR should ensure that the required standards of quality and safety, in the form of QIs for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, are established An action plan to be submitted by the time the PR responds to this report.	Quality Indicators developed – initial plan to randomly audit 25 sets of notes on a 6 monthly basis Audits of QIs commenced. Positive negotiations for a Quality Manager to provide support for the unit	Following review of the action plan submitted by the PR, the inspectorate considers this to be an acceptable response and will continue to monitor progress.

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
A third party agreement did not include identification of persons responsible for managing arrangement between the centre and the third party	The PR should ensure that identification of persons responsible for managing arrangement between the centre and the third party, and review dates are included in	Actions to ensure third party agreements compliant instigated.	The inspectorate considers this to be an acceptable response and will continue to monitor progress.

SLC T114b A third party agreement did not include a review date SLC T114c.	any third party agreement. Evidence of compliance to be forwarded to the inspector by 19 April 2012.		

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

20 April 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 5

Centre 0278 – Assisted Conception Unit, Leigh Infirmary – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Hannah Darby, Senior Policy Manager David Moysen, Head of IT	Lauren Crawford Observing: Paula Robinson, Head of Business Planning Rachel Fowler, Policy & Information Manager

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 the centre had applied for the renewal of its treatment licence and that an inspection of the centre had taken place on 19 January 2012.

2. The Panel noted that the medium sized centre is part of the Obstetric and Gynaecological Directorate of Wrightington, Wigan and Leigh NHS Trust and provides intrauterine insemination (IUI) treatment.

3. The Panel also noted that the centre also provides in vitro fertilisation (IVF) satellite services for CARE Manchester and St Mary's Hospital NHS Trust.

4. The panel noted that, at the time of the inspection, the treatment cycle figures for partner IUI in 2010 was 135 with 16 pregnancies.

5. The Panel noted that, at the time of the inspection, there were two areas of practice that required improvement, comprising one major area of non-compliance and one other area of practice that requires improvement.

6. The Panel noted that, since the inspection, the Person Responsible (PR) has made a commitment to implement both of the recommendations but that one had been identified at the previous inspection and was not yet completed.

7. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

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

The Panel's Decision

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

10. The Panel was satisfied that the qualifications and 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 HF&E Act 1990 (as amended).

11. The Panel noted that the PR has academic qualifications in the field of medicine and more than two years of practical experience. The PR has also successfully completed the PR Entry Programme.

12. The Panel was satisfied that the licence renewal concerns treatment services which relate to gametes or embryos intended for human application.

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

14. The Panel referred to 'Guidance on periods for which new or renewed licences 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.

15. On the basis of the PR's responses to the inspection report and the recommendations identified, the Panel agreed that it had no concerns. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

16. The Panel urged the new PR to address the outstanding recommendations within the agreed timeframes.

Signed ..... Date 3 May 2012

Mark Bennett (Chair)