Inspection Report

Date of Inspection: 25 and 26 January 2012
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 10 hours
Inspectors: Bhavna Mehta; Ellie Suthers

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 23 February 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 (CoP), 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	Lanarkshire Acute Hospital NHS Trust
Centre number	0098
Licence number	L/0098/14/e
Centre address	Infertility Department Monklands Hospital Monkscourt Avenue, Airdrie Lanarkshire, ML6 0JS
Person Responsible	Mr Ian Smith
Licence Holder	Dr Alison Graham
Date licence issued	5 July 2007
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 Lanarkshire NHS Trust infertility department is a small centre based in the Monklands Hospital in Airdrie.

The centre offers NHS funded intrauterine insemination (IUI) with partner sperm and is also licensed for the storage of gametes.

The centre was previously licensed to provide donor insemination (DI) treatment. However, because it had not performed any DI treatment since 2008, the centre applied to the HFEA in 2010 to have this activity removed from its licence. This was approved by the Executive Licensing Panel (ELP) 6 May 2010. The Person Responsible confirmed at this inspection that the only samples in storage are for oncology patients.

The Person Responsible (PR) is the lead biomedical scientist with overall responsibility for scientific activities. The PR is registered with the Health Professions Council and has successfully completed the PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 January 2010 – 31 December 2010*
Intra uterine insemination (IUI)	277

Other licensable activities	✓ or Not applicable (N/A)
Storage of sperm	✓

Outcomes*
For the year 2010 the centre reported 277 cycles of partner insemination with 28 pregnancies. This equates to a 10% clinical 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 – pre review of draft by PR

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 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 no areas of practice that require improvement.

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.

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.

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 and assuring patient identification:

The centre has in place an effective process to ensure that no mismatches of gametes or identification errors occur. Staff at the centre provided documented evidence to demonstrate that they 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 are completed and recorded at the time the relevant clinical or laboratory process or procedure takes place and a record is kept in each patient's record. (SLC T71)

Observation of a sperm processing at the time and an audit of ten laboratory records and ten patient records demonstrated that all double witnessing steps had been completed and recorded appropriately.

Staff at the centre have establish procedures to ensure patients and their gametes are accurately identified and that appropriate evidence to verify the identity of patients in the form of passport photographs were seen to be contained in patient records. (Guidance 18.17) It was observed on inspection that patients are asked to give their own identifying information, positive identification, as part of the witnessing process. (Guidance 18.18)

All samples of gametes in pots, dishes and tubes were seen to be labelled with the patient's full name and a unique hospital number identifier. The labelling of pots, dishes and tubes is witnessed by two members of staff. (Guidance 18.20)

The centre has established quality indicators (QIs) for witnessing and audits of compliance with witnessing requirements are performed annually. The report of the last audit, performed in November 2011, was reviewed on inspection and no corrective actions were required as no non-conformities were identified. (SLC T35 and T36). Staff provided evidence of training in the witnessing process and recent assessments of their competency. (SLC TT15a)

What the centre could do better.
Nothing identified at this inspection.

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.
Patients are referred to the centre by their GP. An audit of patient files on inspection provided evidence that the centre records the justification for treatment, the patient's medical history and any necessary laboratory test results (SLC T49).

Counselling:
All patients are offered the opportunity for counselling prior to treatment.

What the centre could do better.
Nothing identified at this 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.
Quality management system (QMS): Guidance Note 23
Evidence presented indicated that the centre has a well-developed QMS (SLC T32) consisting of a quality manual (SLC T33a), quality policy, regularly reviewed and document controlled SOPs for all key activities (SLCs T33b; T34) and training and reference manuals (SLC T33d). Quality indicator (QI) monitoring of key practices is performed (SLC T35) based on retrospective audit of patient medical records and analysis of laboratory data. The centre has performed practice audits of practice against SOPs, taking corrective actions if QIs breach control limits. The compliance of SOPs with Code of Practice requirements is reviewed annually (SLC T36). The performance of the QMS is reviewed annually by the management team (CoP Guidance 23.13).

Traceability: Guidance Note 19
The PR provided documented evidence to demonstrate that all gametes are traceable from procurement to patient treatment, storage or disposal. (SLC T99) An audit of 10 laboratory records and 10 patient records demonstrated that all equipment and consumables that come into contact with gametes have been recorded. The PR explained that these records will be kept for the requisite 30 years before disposal. (SLC T103)

The PR provided a copy of a reviewed and document controlled traceability policy used by staff; an audit of traceability practice and documented evidence that no corrective actions had been required. (SLC T33 and T36) Staff provided evidence of training in the traceability process and recent assessments of their competency (SLC TT15a).

Validation: Guidance Note 15

Evidence was provided on inspection to show that all critical processing procedures and equipment used in these processes, have been validated on the basis of published studies and centre practice. The validation documentation was reviewed at inspection and was considered by the inspection team to demonstrate compliance with SLC T24 and T72.

Air quality: Guidance Note 25

The PR provided documented evidence to demonstrate that gametes are processed in an environment grade A air quality in the laminar flow hood with a back ground air quality of grade D. A log for 2011 was reviewed at inspection and the PR explained that the air quality is monitored on a monthly basis. The settle plates are now carried out on the recommendation of the consultant Bacteriologist or if there is any reason for concern (SLC T20). Annual calibration and servicing records were provided for the air quality monitoring equipment (SLC T26).

Equipment and materials: Guidance Note 26

The PR provided documented evidence to demonstrate that activities are carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose (SLC T23).

All facilities, equipment and materials used within the centre are purchased, maintained, serviced and monitored through Lanarkshire Acute Hospital NHS Trust .The laboratory's biomedical scientist provided up-to-date and complete logs and checklists to demonstrate the maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises are performed regularly and recorded accordingly (SLC T26).

Documented procedures and manufacturer manuals and guidelines for the operation of each piece of critical equipment and are available to the staff (SLC T27). It was observed during the inspection that SOPs are available via the electronic quality management system and the manuals and guidelines are stored in files in the laboratory.

From observation during the inspection sterile instruments and devices are used for the procurement of gametes, the instruments and equipment are of good quality have been validated and regularly maintained for the procurement and processing of gametes (SLC T28). The cleaning and sterilisation of reusable instruments (specula) is performed via a contract agreement with a local healthcare provider. Documented traceability and quality control was provided at the time of inspection. (SLC T29)

The quality manager provided documented evidence to demonstrate that all consumables are CE marked where possible (SLC T30).

Third party agreements: Guidance Note 24

The centre has established written agreements with those third parties who provide goods (equipment and consumables) that influence the quality and safety of gametes (SLC T111).

An audit of five third party agreements demonstrated that the agreements specify the terms of the relationship and responsibilities as well as the protocols to be followed to

meet the required performance specification (SLC T113).

All of the agreements audited included: a full address and contact details of the third party, and nature of the service to be provided, identification of person(s) responsible for managing arrangement between the centre and the third party, provision setting out how often the agreement will be reviewed and by whom, summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities. (SLC T114)

A complete list of third party agreements is kept and copies made available to the inspection team as part of the application process (SLC T115).

Adverse incidents: Guidance Note 27

The centre is compliant with the HFEA requirements for incident reporting. A review of the centre's incident log confirmed that incidents reportable to the HFEA recorded at the centre correlate with those reported to the HFEA (SLC T118).

What the centre could do better.

Nothing identified at this inspection.

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence, 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.(T/1054/7)

Staff

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 1990 (as amended) Section 17 (1) (a)).

The PR explained that workforce requirements had been assessed within the last year and will continue to be monitored. At the time of inspection, it was reported that the staff complement is sufficient in all disciplines for the current workload (SLC T12).

From the documents reviewed at inspection, the staff were able to demonstrate evidence of the assessment of their competence to perform their designated tasks (SLC T15 (a)).

What the centre could do better.

Nothing identified at this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

The PR and staff provided documented evidence to demonstrate that they take into account the welfare of any child (WoC) who may be born as a result of the treatment and of any other child who may be affected by the birth. (SLC T56) Staff explained that the welfare of any child born as a result of treatment is discussed with the patient and partner at the initial consultation and an HFEA Welfare of the Child form completed, signed and filed in the patients records. Any areas of concern would be discussed at the weekly staff meeting and the patients GP contacted where there is consent from the patient.

An audit of 10 patient records demonstrated that all patients and their partners had completed a welfare of the child assessment and a fully completed and signed assessment form filed in the patients records.

The centre has a documented SOP to guide the WoC assessment (SLC T33(b)) and staff were able to provided good descriptive evidence of their training and competence to conduct WoC assessments (SLC T15 (a)).

The centre has established QIs for WoC assessments (SLC T35) and a quality objective that all patient records should contain a completed copy of the WoC assessment before treatment is commenced. Audits of compliance with requirements are performed annually (SLC T36). The report of the last audit, performed in November 2011, was reviewed on inspection and it identified that no corrective actions were required.

What the centre could do better.

Nothing identified at this 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)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)

What the centre does well.

From evidence provided it appears that staff at the centre ensure that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients.

What the centre could do better.

Nothing identified at this inspection.

Information

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

What the centre does well.

The centre's website and written information were reviewed and were found to be compliant with Chair's Letter CH(11)02 and the relevant CoP requirements.

Information provided prior to consent

From information provided and discussions with staff on the day of inspection, the inspectors conclude that proper information is provided to patients and their partners prior to giving consent to treatment as required by Schedule 3 (1) (b) of the HF& E Act 1990 (as amended). Staff who are involved in the information giving process confirmed that prospective patients are sent all relevant consents and related written information regarding their proposed treatment. The proposed treatment and its implications are then discussed.

What the centre could do better.

Nothing identified at tis inspection

Consent

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

What the centre does well.

Staff at the centre provided evidence to demonstrate that appropriate written consent is obtained by suitably qualified and competent staff before gametes or embryos are used in treatment (SLC T57).

Consent to treatment, storage, donation, training and disclosure of information

At inspection an audit of 10 sets of patient records demonstrated that all had correctly completed consent forms; all had completed and documented identity verification.

The centre has established a QI requiring 100% of all patients to have appropriately signed consents in place before commencing treatment (SLC T35). An audit of consenting practice was conducted in November 2011 and the audit report recorded that corrective action was required to remind all staff to check that the checklist in the patient's record is completed. A review of the five patient files, following the audit, demonstrated that this corrective action has been implemented (SLC T36).

What the centre could do better.

None identified at this inspection.

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.

Following a tour of the licensed centre 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 the precincts to which that licence applies.

What the centre could do better.
Nothing identified at this inspection.

Storage of gametes

- Storage of gametes (Guidance Note 17)

What the centre does well.

The centre provides storage facilities for gametes from patients undergoing chemotherapy. Staff provided evidence to show that they no longer provide donor insemination services or storage of gametes for sibling use.

The PR provided evidence to demonstrate that all gametes in storage at the centre are stored in accordance with patient consents and that the centre has written effective consent for the storage of all gametes currently in store (HFE Act 1990 (as amended) Schedule 3, 8 (1).

Staff at the centre operate an effective bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period for gametes in storage. (Guidance 17.17)

Prior to the storage of gametes patients are screened for HIV, Hepatitis B and Hepatitis C and when storage is necessary prior to the screening tests being available there is a system of quarantining for the unscreened gametes. An audit of 10 patient records showed that all patients had been screened in accordance with SLC T50. The screening is requested carried out by the oncology centre referring the patient and evidence was provided to demonstrate that screening tests were carried out by a CPA (UK) accredited laboratory. (SLC T51)

The storage facilities for gametes are dedicated for the purpose, and adequate for the volume and types of activities; has emergency procedures to deal with damage to storage

vessels, failure of storage conditions or both. (Guidance 17.2 and17.3)

The centre has effective alarms and monitoring systems to ensure the safety of cryopreserved gametes. These systems were seen to have local alarms: an auto-dial facility to contact staff outside normal working hours: adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and adequate spare storage space or vessels to enable transfer of samples if a vessel fails. (Guidance 26.4)

Staff at the centre have documented procedures (SOP) to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient consent. (SLC T33).

What the centre could do better.

Nothing identified at this inspection.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes (Guidance Note 15) – *only applicable for distribution of gametes*

What the centre does well.

Distribution of gametes and embryo

The PR explained that the distribution of gametes is limited to the, infrequent, receipt of samples from patients storing their sperm prior to oncology treatment and then transfer of cryo preserved sperm to other HFEA licensed centres for treatment. Sperm is transported either by the centre staff or by the staff providing treatment to the patients.

The centre has a SOP describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLCs T33 (b) and T107). The centre uses receipt and dispatch checklists to ensure the procedure is followed accurately and that all required information is provided, as evidenced during the review of a completed checklist for the receipt of imported sperm (SLC T110). The dispatch checklist includes the requirement to: record the date and start time of transport (SLC T107); seal the container with a security tag prior to transport (SLC T108) and submit gamete movement forms to the HFEA (General Direction 0005).

The SOP also defines the responsibilities and actions that are required if a distribution is recalled, including the investigation of the recall as an adverse incident (CoP interpretation of mandatory guidance 15C).

What the centre could do better.

Nothing identified at this 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. 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 services 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 identified at this 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. **Obligations and reporting requirements of centres** 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.
What the centre could do better. Nothing noted at the time of this inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

Confidentiality and privacy

Discussions held with staff, a review of information submitted for the inspection and a tour of the premises, indicated that information about patients is not disclosed unless under circumstances permitted by law (SLC T43).

What the centre could do better.

Nothing noted at the time of this inspection.

5. Changes / improvements since the previous inspection on 23 February 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Witnessing The centre's witnessing records include the signature but not the name and status of the person performing the activity and the person witnessing the activity. Licence Condition T71 and CoP 18.8.	The PR should ensure that witnessing records include the name and status of both the person performing the activity and the person who witnesses the activity. Compliance with this requirement could be achieved by maintaining a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.	The revised form was submitted after the last inspection and includes space for name, status and signature. A review of a sample of patient records at this inspection confirmed that this action has been taken. No further action required.
Procurement of gametes and embryos When the sperm was procured at home, the centre had not recorded this in the patient records. Licence Condition T68.	When the sperm is procured at home, the PR should ensure that this is recorded in the sperm provider's records.	The revised form was submitted after the last inspection and includes space for recording place of procurement. A review of a sample of patient records at this inspection confirmed that this action has been taken. No further action required.
Adverse incident reporting The centre was not aware that cases of OHSS graded as severe or critical and requiring hospital admission should be reported to the HFEA as adverse incidents. Licence Condition T118, General Directions 0011 and CoP 27.1.	The PR should ensure that OHSS cases that have a severity grading of severe or critical and require hospital admission are reported to the HFEA as adverse incidents, within the timeframes specified in General Directions 0011. The PR should report the 2 recent cases of OHSS retrospectively and ensure that staff receives training on reporting adverse incidents.	The two cases were retrospectively reported in May 2011. At this inspection, evidence of training on reporting incidents was seen logged in staff training files. No further action required.

Personnel There was no documented evidence that staff had been assessed of their competence to carry out witnessing. Licence Condition T15(a) and CoP 2.1(b).	The PR should ensure and document that each individual has demonstrated competence in the performance of their designated tasks and should establish a documented procedure for on-going competence assessment.	The Executive considers this response to be sufficient. No further action required.
Legal parenthood Staff interviewed were not aware of changes brought about by the HF&E Act 2008 in relation to legal parenthood. Licence Conditions T60 and T61.	It is acknowledged that the centre has not provided any treatment using donor sperm since the last inspection and therefore this has not had an impact on patients. However the centre is licensed to provide treatment using donor gametes and the PR should ensure that all staff, including the counsellor, are informed of legal parenthood requirements. The PR should put a protocol in place for providing legal parenthood information to patients.	The Executive considers this response to be sufficient. 6 May 2010 ELP minutes: “The Panel noted that in the inspection report pertaining to item 4 of this meeting, the inspectorate made a recommendation in relation to staff training on legal parenthood. The Panel noted that if donor insemination (DI) is removed from the centre’s licence that this recommendation would no longer be relevant. DI was removed by the ELP, therefore 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			

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
None			

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
None			

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 3

Centre 0098 – Lanarkshire Acute Hospital NHS Trust – 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,

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 (insemination using partner / donor sperm) and storage licence and that an inspection of the centre had taken place in January 2012. The form in the papers described a different type of licence and so the type of licence to be renewed and agreed by the Panel was confirmed subsequent to the meeting by reference to the current active HFEA licence and the scope of activities covered during the inspection.

2. The Panel noted that this centre is based in the Monklands Hospital in Airdrie and provides NHS funded intrauterine insemination (IUI) with partner sperm and is also licensed for the storage of gametes.

3. The Panel also noted that the centre was previously licensed to provide Donor Insemination (DI) but, in 2010, had this removed from its licence as it had not been performed since 2008.

4. The Panel noted that, at the time of the inspection report, the treatment cycle figures for partner IUI in 2010 was 277 with 28 pregnancies.

5. The Panel noted that, at the time of the inspection, there were no areas practice that required improvement and that this reflected well on the PR and clinic staff.

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

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

The Panel's Decision

8. 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.

9. 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).

10. The Panel noted that the PR is the lead biomedical scientist with overall responsibility for scientific activities. The PR is registered with the Health Professions Council and has successfully completed the PR Entry Programme (PREP).

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

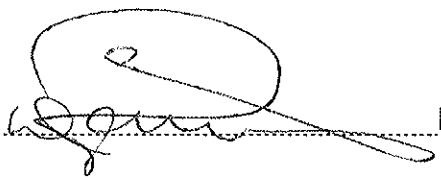
12. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

13. The Panel noted that the application does not involve the use of embryos for training purposes.

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. The Panel agreed that, due to there being no recommendations made and no areas of non-compliance or poor practice noted in the report, it had no concerns about granting the licence for four years.

16. The Panel agreed to renew the centre's licence for treatment (insemination using partner / donor sperm) and storage for a period of four years with no additional conditions.

Signed  Date 15/5/12

Mark Bennett (Chair)