Inspection Report

Date of Inspection: 8 December 2011
Purpose of inspection: Licence Renewal - Treatment (Insemination using Partner Sperm)
Length of inspection: 5.30 hours
Inspectors: Bhavna Mehta; Paula Nolan

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 14 January 2010 and 3 January 2012

Date of Executive Licensing Panel: 27 January 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	Epsom And St Helier NHS Trust
Centre number	0259
Licence number	L0259/3/b
Centre address	Assisted Conception Unit, Womens Health, St Helier Hospital, Wrythe Lane, Carshalton, Surrey, SM5 1AA,
Person Responsible	Dr Elizabeth Sherriff
Licence Holder	Dr Rim Elrifai
Date licence issued	1 July 2010
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 (ACU) at Epsom and St Helier University Hospital provides intrauterine insemination (IUI) treatment to NHS and self funded patients and has been licensed since July 2007. The centre operates from premises within the Women's Health Services Department of St Helier Hospital and shares some facilities with the Gynaecology Outpatient's Department.

The centre provides transport services for The Bridge (0070) and ACU Kings College (0109) centres.

Activities of the Centre:

Type of treatment	Number of treatment cycles in 2010*
IUI (P)	11

Outcomes*

For the year 2010 the centre reported 11 cycles of partner insemination with three pregnancies.
As the activity rate is below 50 cycles no percentage rates are provided.

*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 her 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 there are no areas of practice that require improvement.

The inspection team recommends the renewal of the centre's licence for a period of four years.

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 identification (Guidance Note 18)

What the centre does well.

The centre has a documented SOP which describes the unit's witnessing practice. This SOP specifies the witnessing steps to be carried out in clinical and laboratory practice (Standard Licence Condition (SLC) T33b).

The centre has established quality indicators (QIs) and objectives relevant to witnessing (SLC T35). Audits of patient records are also conducted to verify that witnessing checks are performed and recorded. Any errors or omissions are documented and corrective actions taken. The witnessing procedures were audited every six months against compliance with the protocols, the regulatory requirements and quality indicators (SLC T36). The witnessing audit report was reviewed at inspection and detailed no corrective actions since no non-conformities were identified.

The inspector conducted an audit of the centre's witnessing and patient identification practice by reviewing a sample of patient files. All the files reviewed contained records of witnessing at all required steps and appeared to be compliant with requirements.

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)

What the centre does well.

Discussions with staff and documentation provided by the centre demonstrated, to the satisfaction of the inspectors, that all patients are selected on the basis of the patient's medical history and therapeutic indications in accordance with professional body guidelines and locally agreed commissioner treatment criteria, and that the rationale for treatment is recorded in the patient's medical records (SLC T49).

Discussions with the staff and a review of five patient files confirmed that the diagnostic semen analysis is undertaken in the hospital's laboratory which has been accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T21).

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.
The centre's staff provided information and evidence to show that the centre follows good clinical practice and has suitable premises and equipment for the treatment services offered.

Quality Management System

The centre has a QMS and quality manual in place (SLCs T32 and T33). The centre provided an index list of all QMS documents prior to inspection and a sample of documents were viewed as part of this inspection process. Staff reported that any changes in procedures are discussed at staff meetings and training provided to ensure consistency.

The centre has set quality objectives of 100% compliance with CoP requirements for 2010/11 (SLC T 35). The audit report was reviewed at inspection. This showed that audits are carried out every six months for licensed activities, except for the provision of information which is audited every four months. The audits are conducted by staff to verify that the witnessing checks are carried out as required by the CoP; that the correct and relevant information has been given to patients, that Welfare of the Child (WoC) assessments are documented correctly and that the correct consent to treatment form has been completed and recorded in the patient's file. Any errors or omissions were documented and corrective actions have been implemented (SLC T36).

Traceability
The centre's traceability SOP was reviewed and describes the process by which traceability of consumables and reagents which come into contact with gametes is ensured, (SLC T33b).

The centre's logs of all reagents and materials used were reviewed on inspection and demonstrated that all relevant traceability data is recorded. A spot check of consumables in use in the laboratory against those recorded as being in use in the laboratory logs demonstrated that data is recorded accurately (SLC T102).

Validation of equipment
The quality manager provided evidence to demonstrate compliance with the requirement that all critical equipment has been validated (SLC T24). The centre has contracts for the maintenance and regular servicing of equipment. The service records list was reviewed at inspection which documents the centre's critical equipment.

The inspector observed that key equipment, critical to the processing of gametes, is subject to appropriate monitoring (scheduled preventative maintenance, regular calibration and parameter monitoring) (SLC T24). Staff were able to confirm that all consumables in use in the laboratory are sterile and CE marked where applicable. (SLC T30).

Validation of processes:
At inspection staff explained that the procedures for sperm preparation, insemination and the intervals between the testing of the air quality, have been validated (SLC T72).

The quality manager provided documented evidence to show that work had been carried out to validate critical processes based on a retrospective review of the centre's own experience compared with the processes of the licensed centres with whom they have transport arrangements and with reference to published studies (SLC T72).

Premises – suitability of the premises and air quality
A tour of the centre confirmed that licensable activities are carried out on the licensed premises which are within the same building (HF&E Act S.12 (1) and SLC T1).

Documented evidence of the centre's cleaning logs reviewed at inspection demonstrated compliance with this requirement (SLC T26).

The centre's air quality is monitored annually by an external company. Documented evidence, dated October 2011, was provided on the day of inspection that the processing of gametes takes place in an environment of grade A air quality in the critical work area with a background environment air quality of grade C (SLC T20).

Third party agreements
The centre staff were able to demonstrate that there are third party agreements in place for all goods and services that influence the quality and safety of gametes and the agreements were available for review on the day of inspection (SLC T111).

Adverse incidents
The centre has documented procedures for reporting serious adverse events and

reactions that may occur (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 medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years 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 T/1112/7).

Staff

The other consultant at the centre is also registered with the GMC and is on the specialist register for Obstetrics and Gynaecology.

The quality manager 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). She explained that all staff have professional body registration checks, as per the Trust human resources policy, prior to employment. She also confirmed that continued professional body registration is also periodically checked and all staff members participate in induction and on-going mandatory training as determined by the Trust policy. The centre has a local policy in addition to support the staff professional development and performance appraisals (SLCs T12 and T14).

A review of documentation provided pre-inspection, including the centre's management review provided evidence that the workforce requirements had been assessed within the last year and will continue to be monitored. (SLC T12).

The nurses are registered with the Nursing and Midwifery Council (SLC T14).

From the documents reviewed at inspection, the staff were able to demonstrate evidence of the assessment of the 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.

From discussions with staff, a review of the welfare of the child (WoC) information provided by centre staff, observation of nurse interviews with two patients and a review of patient records, the inspectors conclude that before any woman is provided with treatment services; proper account is taken of the welfare of any child who may be born as a result of treatment and of any other child who may be affected by the birth (SLC T56). The clinical staff were able to appropriately describe the process for conducting a WoC assessment and their actions in the event that matters of concern arise, giving examples of how this has been managed with specific case instances.

Five sets of patient records were audited on inspection. In each instance the file contained WoC questionnaires completed by the patient and partner and also evidence of their review by a member of staff prior to the commencement of treatment.

The centre has established a QI that all patient records should contain a completed copy of the WoC assessment for each partner before treatment commencing. 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, including observation of practice (SLC T15 (a))

The centre's audits its WoC practice (SLC T36) every six months and the last audit report documented that no errors were noted and no corrective actions 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)
- Provision of costed treatment plans (Guidance Note 4)

What the centre does well.

Treating patients fairly

Members of staff reported that there are policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner and that careful consideration is given as to how the centre may meet the needs of individual patients and their circumstances (GN 29).

Confidentiality and privacy

A tour of the centre confirmed that all confidential information is stored securely with access restricted to authorised personnel only. Areas where conversations personal to individual patients and partners may occur were seen to be private and opportunities to be overheard reduced to a minimum.

All staff are asked to read and sign a confidentiality agreement on the maintenance of confidentiality (SLC T43). Maintaining confidentiality also forms part of the Trust mandatory induction and training (SLC T15 (a)).

Complaints

The centre has a complaints policy and information on how service users may make a complaint is displayed in patient areas. Staff described the process for dealing with complaints. The centre's complaint's log, reviewed at inspection, showed that the centre has received two complaints from patients regarding communication. The centre has taken corrective actions and these were discussed at inspection (GN 28.1).

Provision of a costed treatment plan

The centre offers treatment to self–funding patients. At the time of inspection, self-funding patients and their partners were being given clear written information regarding the anticipated costs of their treatment based on the NHS fees structure GN 4.3. This provision of this information is recorded in each patient's file on the standard tick list used by the centre.

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.

Staff explained that patients are provided with information about the centre and success rates. Other information is provided as relevant to the treatment. The centre submitted the patient information as part of this licence renewal application. This information was audited prior to inspection and found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality and consent.

The website was also reviewed and found to be compliant with Chair's letter CH(11)02.

What the centre could do better.

Nothing identified at this inspection.

Consent

- Consent to treatment (Guidance Note 5)

What the centre does well.

Information provided prior to consent

From information provided, a review of patient records and discussions with staff and observations 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 implications of that treatment are then discussed at separate one to one consultations with the clinician directing their treatment.

Five sets of patient notes were reviewed at inspection and appropriate consents were in place in all cases.

What the centre could do better.

Nothing 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.

Distribution of gametes and embryos • Distribution of gametes and embryos (Guidance Note 15) –*applicable as centre that has distributed gametes*
What the centre does well.
What the centre could do better.

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 and partner records seen at the time of inspection were considered to be legible and well organised. Each record reviewed included a copy of the person's passport which is retained for identification purposes. Each record seen also provided details of the person's medical history, WoC documentation, clinical and laboratory test results and relevant documented consent forms (SLC T46). The staff member responsible for the management of medical records confirmed that records are protected from unauthorised amendment and are retained securely (SLCs T47). Patient records are kept for 30 years in line with Trust policy. (SLC T48)
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. The PR has responded fully with the recommendations from previous inspections. Data submissions are submitted as required.
What the centre could do better. Nothing identified at this inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

From discussions with staff, a tour of the centre premises and facilities and from documentation seen, the inspection team conclude that the centre ensures information about people who are receiving or have received treatment and children born as a result of assisted conception is not disclosed unless authorised to do so and that the dignity and privacy of those being treated or donating gametes is protected at all times (SLCs T43 and T33(b)).

What the centre could do better.

Nothing identified at this inspection.

5. Changes / improvements since the previous inspection on 14 January 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Procurement and processing (guidance note15): A programme for validation was reported by the PR to have been commenced. Evidence during the inspection suggested that to date no equipment had been validated and the only critical process to have been commenced was IUI, this being in the beginning stages of the validation process (T72). This was discussed with the PR and QM who expressed willingness to commence and complete this programme but reported that they had both been unable to negotiate to increase the time spent in their respective roles and this is inhibiting their ability to take on large projects. The QM requested advice regarding the implementation of a validation programme and expressed her intention to refer to the Association of Clinical Embryologists validation information and templates. **This was an issue raised at the last inspection on 15 February 2009.**	The PR should implement a programme to validate all critical equipment and processes at the centre. The PR should submit to the HFEA a quarterly report on the progress of this programme until it is complete. To commence immediately.	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Good clinical practice No further action required.
Quality management The centre does not have any quality indicators to measure the required standards of quality and safety of licensed activities	The PR should develop quality indicators to measure the required standards of quality and safety of	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed.

as required by T35.	licenced activities. To be completed by 14 May 2010	Update from this inspection – see above section 1. Protection of patients and children born following treatment -Quality management system. No further action required.
Witnessing (guidance note 18): During the inspection five sets of patient records were audited for compliance with witnessing requirements. Two sets were found not to include a space to record the times of all witnessing steps. Of the five sets of records audited the sperm preparation witnessing step appeared to have been omitted in one case (T71).	The PR should carry out an audit of witnessing documentation within patient records with the aim of identifying any further discrepancies. She should use the findings of this audit to identify any areas where the SOP or staff training could be amended to minimise the risk of recurrence. The results of this audit should be submitted to the HFEA. To be completed by 14 May 2010	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Witnessing and assuring patient identification. No further action required.
Third party agreements (guidance note 24): While at inspection it was observed that all Third Party Agreements are now in place (T111), these did not appear to contain sufficient detail as to the terms of the relationship and responsibilities between the parties and the protocols to be followed to meet the required performance specification (T113/T114).	The PR should ensure that all third party agreements contain such detail as required by T113 and T114. By 14 January 2011	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Good clinical practice No further action required
Premises and Facilities: (guidance note 25): The sperm processing room and hood have been assessed for air quality once and was found to be compliant with the requirements of T20, evidence of these results was provided by the QM during the inspection. However, this process has	The PR should facilitate the validation of the air quality monitoring programme including the interval for repeat monitoring. By 14 May 2010	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Good clinical

not been validated and the PR was unable to provide justification for opting not to test for fluctuations when the monitoring programme was commenced or for the choice to monitor air quality at annual intervals. (T72). T72		practice No further action required.
Staff (guidance note 2): While staff appeared to be qualified to perform designated tasks at the centre records of ongoing evaluation or review of their key competencies were incomplete. The professional development folders of the most senior and the most recently employed nurses were provided at inspection and while one nurse had been assessed for IUI and scanning and the other for consenting, other key competencies including witnessing, sperm preparation and emergency procedures did not appear to have been assessed at regular intervals (T12/T15). **This was an issue raised at the last inspection on 15 February 2009**	The PR should commence a programme to review and assess the competence of all staff at the centre. By 14 May 2010	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Staff engaged in licensed activity No further action required
Records (guidance note 31): While all documents provided to the HFEA before the inspection and observed on the day were noted to be within their document control review dates, the period for review in most cases appeared to be two years rather than annually, as recommended by G31.6.	The PR should consider amending the centre's document control procedure to include annual review of all documents. By 14 May 2010	In November 2011, the PR confirmed by letter that all actions required in the previous inspection report had been completed. Update from this inspection – see above section 1. Protection of patients and children born following treatment - Good governance and record keeping 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
I have read your report and do not feel there is any additional information i need to add. I delighted that the teams hard work over the last two years to bring the unit in line with all the HFEA recommendations has been appreciated by the HFEA inspection team.

HFEA Executive Licence Panel Meeting

27 January 2012

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

Minutes – Item 1

Centre 0259 – (Epsom and St Helier NHS Trust) –Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Danielle Hamm – Senior Policy Manager	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 centre provides intrauterine insemination (IUI) treatment to NHS and self-funded patients and has been licensed since July 2007.

2. The Panel noted that the centre also provides transport services for The Bridge (Centre 0070) and ACU Kings College (Centre 0109).

3. The Panel noted that during 2010 the centre reported 11 cycles of partner insemination which resulted in three pregnancies. The Panel noted that as the centre's activity rate is below 50 cycles no percentage rates are provided.

4. The Panel noted that during the inspection the Inspectorate identified no areas of practice that required improvement.

5. The Panel noted the improvements made by the centre since it was last inspected in 2010.

6. The Panel noted the PR's positive response to the inspection report.

7. The Panel noted that the Inspectorate recommends the renewal of the centre's licence for a period of four years with no additional conditions.

Decision

8. 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.

9. The Panel was satisfied that the qualifications and character of the PR are 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.

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

11. 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.

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

13. 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 response to the inspection and the absence of identified non-compliances, the Panel agreed that it had no concerns.

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

Signed: Peter Thompson Date: 7/2/12
Peter Thompson (Chair)