Interim Licensing Report

Centre name: **Herts and Essex Fertility Centre**

Centre number: **0030**

Date licence issued: **1 October 2011**

Licence expiry date: **25 November 2014**

Additional conditions on licence: **None**

Date of Inspection: **12 June 2012**

Inspectors: **Janet Kirkland, Andrew Leonard**

Date of Executive Licensing Panel: **21 September 2012**

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service:** the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note:

- the positive comments received from patients to the HFEA in questionnaires received prior to the inspection and in discussions with the inspector on the day of the inspection.
- the PR's response post inspection to recommendations and the submission of all requested SOP's and documentation prior to presentation to the Executive Licensing Panel

The Executive Licensing Panel is asked to note that at the time of the inspection there were recommendations for improvement in relation to one critical area of non-compliance, three major areas of non-compliance and nine other areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implement all of the following recommendations made in the report and has submitted all of the requested documentation:

'Critical' areas of non compliance:

- **the PR should ensure that no gametes or embryos are kept in storage for longer than the consented period (T82a)**

'Major' areas of non compliance:

- the PR should ensure that the disposal of gametes is witnessed (CoP Guidance 18.33);
- the PR should ensure that if the centre has laboratories or contracts with third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard (SLC T21);
- the PR should document a procedure which ensures that if a woman withdraws her consent to her nominated second parent being treated as the legal parent or consents to a different person being the legal parent of any child resulting from treatment, the PR notifies the original nominated second parent in writing of this (SLC T65);

It is noted that the second two areas identified here as 'major' areas of non-compliance have been classified as such because they were cited in the report of the last inspection in July 2010 and found to be outstanding at this inspection.

‘Other’ areas of practice that require improvement:

- the PR should ensure that all dishes/tubes used for a patient’s gametes are labelled at all times (SLC T101);
- the PR should audit how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators (SLC T36);.
- the PR should ensure that a procedure is in place for handling returned gametes and embryos in addition to the investigation of any recall as an adverse incident (CoP interpretation of mandatory requirements 15);
- the PR should ensure that a procedure is in place to ensure that prior to giving consent for use of embryos in training, each gamete provider is provided with the necessary information on the nature of the training for which embryos will be used and whether any information will be fed back to them (SLC T97);
- the PR should review the position whereby a specific cohort of patients, i.e. those who are commissioned by the NHS, are not routinely screened for anti-HBc due to commissioner funding issues (SLCT50);
- the PR should audit a sample number of patient and partner consents to disclosure of identifying information to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent(SLC T36);
- the PR should ensure that anyone seeking treatment or considering donation or storage is given enough time to reflect on their decisions before obtaining their consent and has an opportunity to ask questions and receive further information, advice and guidance (CoP Guidance 5.6);
- the PR should ensure that data which the Authority is required to hold on its Register is provided within the timescales specified in General Direction 0008;
- the PR should perform an audit of patient records for the accurate completion and documentation of Welfare of the Child (WoC) assessment (SLCs T36);

Information about the centre

The Herts and Essex Fertility Centre is located in Cheshunt and has held their current HFEA licence since November 2010. The centre was formerly known as Essex Fertility Centre and was located at Holly House Hospital and has been licensed by the HFEA continuously since 1992.

The centre provides a full range of fertility services.

The centre provided 1424 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to April 2012. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA Register data for the year ending 31 January 2012 show the centre's clinical pregnancy rates are in line with national averages for IVF, ICSI, and frozen embryo transfer (FET) treatment cycles in all age groups.

For the year 2011 the centre reported 21 cycles of partner IUI with 2 pregnancies. This equates to a 9 % success rate. This is consistent with the national average pregnancy rate.

Multiple births[2] (SLC T123)

The single biggest risk of fertility treatment is multiple pregnancy. In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represented performance that was not likely to be statistically different from the 20% multiple live birth rate target.

Between 1 April 2011 and 31 March 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%: this also represents performance that is not likely to be statistically different from 15% multiple live birth rate target.

The increase in clinical multiple pregnancy rates from 2010/11 to 2011/12 is noted. This suggests that the centre's strategy may need review if the centre is to meet the more stringent target that comes into force in October 2012.

[1] 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.

[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Witnessing (SLC T71)
Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; thawing of gametes; sperm preparation and preparation for embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system, supplemented with manual witnessing where necessary. The inspection team was able to review records that were present in the laboratory and concluded that records of both manual and electronic witnessing are maintained.

It was however noted that the tubes and dishes used during egg collections are not marked with patient identifiers (SLC T101).

Consent : Disclosure to researchers (General Direction 0007)
A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent. The records of consent to disclosure to researchers given by nine patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all but one of the records reviewed.

In the record concerned a relevant section of the form had not been completed, however, the record held on the HFEA register reflects that consent to disclosure has been given. Where the relevant section of the form has not been completed the intention of the patient and her partner is unclear.

Consent: To the storage of cryopreserved material (Human Fertilisation and Embryology (HFE) Act 1990 (as amended), Schedule 3, 2 (2)).
On inspection, the PR reported to the inspection team that an audit of the centre's records of consent to storage of gametes and embryos conducted prior to the inspection, showed that embryos belonging to two couples were being stored beyond their consented period. The PR confirmed that one set of stored embryos had subsequently been allowed to perish but that the second set of embryos remained in storage. The circumstance surrounding the continued storage of these embryos were described by the PR. The inspection team were satisfied that the centre anticipated the position would be resolved within days pending the receipt of legal advice by one of the gamete providers. Both of these occurrences had been reported to the HFEA as incidents by the PR at the time they were discovered. The PR recognises that these incidents also highlighted the need for a more robust system and implementation of the centre's 'bring forward' system.

Staffing (SLC T12)
Having the right numbers of staff, competent to carry out highly technical work in non-pressured environment is important in infertility services. Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to a number of patients who provided feedback on their experiences, and observed interactions between centre staff and patients. A further 34 patients have also provided feedback directly to the HFEA in the time since the last inspection in July 2010.Feedback was positive with 27 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to conclude that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

It was also noted however from patient feedback and observations on inspection that patients are asked to complete consent forms during the information-giving appointment and may therefore not have sufficient time to reflect on their decisions and discuss them further as a couple where relevant .

The SAQ submitted by the PR indicated that the centre has not in the last two years audited how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators .

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to the HFEA.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire (SAQ) and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- a specific cohort of patients are not routinely screened for Anti-HBc
- the centre does not have a procedure for handling returned gametes and embryos or for the investigation of any recall as an adverse incident
- the centre does not have a procedure which ensures that each gamete provider is provided with the necessary information on the nature of the training for which embryos will be used and whether any information will be fed back to them about the use of their embryos in training ;
- in the last two years the centre has not audited how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators ;
- during an audit of six patient records on the day of inspection it was noted that in one instance treatment had been provided without the WoC documentation being signed by the clinician.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2010, recommendations for improvement were made in relation to five major non-compliances and two 'other' areas on non-compliance or areas of poor practice. It was identified on this inspection that all but the following recommendations have been fully implemented:

- The PR should ensure if the centre has laboratories or contracts with third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard .
- the centre does not have a documented procedure to ensure that if a woman withdraws her consent to her nominated second parent being treated as the legal parent or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this ;

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. At the time of the inspection the HFEA register team reported that:

- the submission of a significant number of intention to treat forms (ITT) is outstanding;
- in three instances of treatments in which donor gametes were used the HFEA has not received data on the pregnancy outcome;
- 22% of treatment forms and a number of pregnancy outcome forms were received late during the month of May 2012.

Annex 1

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 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	Inspection team's response to the PRs statement
1) Storage of gametes and embryos. An audit of stored material performed prior to inspection identified two instances of embryos being stored where the consents to storage had expired (SLC T82a).	The PR should review the systems and procedures that are in place to identify where gametes/embryos are nearing the end of the consented period. A summary report of the findings of the review and any corrective actions, including a timescale for their implementation should be submitted to the HFEA by 3 September 2012.	The embryos in question have been discarded. No further embryos or gametes are in storage with out proper consent. A review had already been undertaken and new systems have been implemented which is how the two instances of embryos in storage beyond the consented period had been highlighted. As PR I will	The inspector notes the PR's comments . SOP "gamete embryo storage review " and three additional related SOP's were received by the inspector on 6 September 2012. No further action.

	The HFEA should be notified of any decisions made in relation to the on-going storage of embryos where the consent to storage has expired.	conduct a full review of the process and this will be forwarded on to you before 3/9/2012	

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 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	Inspection team's response to the PRs statement
1) Disposal of Gametes The disposal of semen samples and unfertilised oocytes is not witnessed (CoP 18.33)	The PR should ensure that the disposal of semen samples not used in treatment and unfertilised oocytes is witnessed. This recommendation should be implemented with immediate effect and a S0P submitted to the inspector by 3 September 2012.	We have now incorporated the the witnessing of the disposal of unused gametes into our electronic witnessing systems and in the process of adapting the necessary paper work to ensure full compliance. I will provide all the necessary paper work prior to 3/9/2012	SOP received 6 September 2012 No further action

2) Premises and facilities The centre uses an external pathology laboratory for blood testing which is not CPA accredited. This was identified as an area for improvement at the last inspection (SLC T21).	The PR should provide evidence that the external pathology laboratories are working towards accreditation and update the inspector quarterly regarding progress towards accreditation. This recommendation should be implemented by 3 September 2012.	The HFEA is aware that the pathology laboroatory is in the process of obtaining the ISO 15189 accreditation. The laboratory has completed a pre-assessment as part of the application process and I have seen the report which clearly refelects the work they need to do prior to the full inspection that they are expecting end of Sept/early Oct. As PR I am prepared to wait until this inspection has been completed before we decide whether to continue with them. The level of service this facility provides currently is first class. I will update you regularly with their progress.	The Inspector is satisfied with this response. The PR has also supplied the inspector with evidence that the external pathology laboratory is working towards accreditation. The progress of the laboratory towards accreditation will be monitored in the compliance cycle.
3) Legal parenthood According to the self assessment questionnaire (SAQ) the centre does not have a documented procedure to ensure if a woman withdraws her consent to her nominated second parent being treated as	The PR should develop and document an SOP to ensure if a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment,		SOP received by inspector on 29 June 2012 No further action

the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this (SLC T65). This was identified as an area for improvement at the last inspection.	that the PR notifies the original nominated second parent in writing of this (T65). This recommendation should be implemented by 3 September 2012 and the changes made notified to the lead inspector.		

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	Inspection team's response to the PRs statement
1)Traceability and coding The tubes and dishes used during egg collection are not marked with patient identifiers (SLC T101).	The PR should either ensure that the plastic ware is all appropriately labelled during egg collection, or should ensure the practice is risk assessed and that the laboratory SOP for egg	We have updated the egg collection and witnessing sop to accommodate a change in practice which requires us to have a witness to confirm that all carrier test tubes and dishes used during an	The Inspector has considered the response and received the SOP on 6 September 2012. No further action.

	collection states that only one person's gametes should be in the critical work area at a time and that the air flow cabinet must be emptied of all plastic ware and cleaned between each egg collection. A summary report of the review and corrective actions implemented should be provided to the HFEA by 3 September 2012	egg collection are discarded prior to the next egg collection commencing. This new witness point circumvents the need to label the tubes.	
2) Quality Management The centre has not in the last two years audited how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators (SLC T35)	The PR should audit how far procedures to ensure that all information is kept confidential comply with the approved protocols, regulatory requirements and quality indicators. This recommendation should be implemented by 3 September 2012 and the lead inspector notified of the results of the audit.	A full audit of confidentiality has been carried out and a full report of that audit will be provided on the 7 Sept.	Audit received on 6 September 2012. No further action.

3) Import, export and transportation/distribution of gametes and embyros The centre does not have a procedure for handling returned gametes and embryos or for the investigation of any recall as an adverse incident (CoP interpretation of mandatory requirements 15).	The PR should develop and document a procedure for handling returned gametes and embryos and the investigation of any recall as an adverse incident. This recommendation should be implemented by 3 September 2012 and the lead inspector provided with a copy of the documented procedure.		SOP received by inspector on 29 June 2012. No further action.
4) Use of embryos for training staff The centre does not have a procedure which ensures that prior to giving consent, each gamete provider is provided with the necessary information on the nature of the training for which embryos will be used or whether information will be fed back to them regarding the use of their embryos in training (SLC T97).	The PR should ensure that a procedure is available which ensures that prior to giving consent each gamete provider is given the necessary information on the nature of the training and whether information will be fed back to them regarding the use of their embryos in training.		SOP received by inspector on 29 June 2012. No further action.

	This recommendation should be implemented by 3 September 2012 and the lead inspector provided with the SOP		
5) Patient selection criteria and laboratory tests Due to funding issues NHS commissioned patients are not routinely screened for Anti-HBc (SLC T50)	The PR acknowledges this non-compliance but assured the inspection team that all self-funded patients and all donors are screened. As the centre will soon no–longer be in a position to provide treatment for NHS funded patients, the situation should no longer be an issue. The PR should however consider reviewing this situation as and when the centre resumes treating NHS commissioned patients and should advise the centre's inspector when this occurs.	All our self funded patients are screened Anti-HBc, it is only the NHS funded patients that were not screened for anti-HBc purely because the screening was done prior to the referral and costed accordingly. The NHS contract had not taken into account the new EUTD requirement and so patients were only screened for HBsAg. All patients are now screened for Anti-HBc as will all future NHS patients.	The Inspector is satisfied with this response. No further action.
6) Consent to disclosure An audit of records for consent to	The PR should check that appropriate systems and	I have completed a full audit of the consents and	Audit received on 6 September 2012.

disclosure highlighted one record where a relevant section of the form had not been completed, though the register reflects that consent has been given. Where the relevant section of the form has not been completed the intention of the patient and their partner is unclear (General Direction 0007)	processes are in place to ensure that the consents to disclosure are appropriately explained, are checked post completion and that the data is accurately transferred to the register. This recommendation should be implemented by 3 September 2012 and the lead inspector notified of results of the review and any actions taken.	the welfare of the child assessments. The findings and action points for this audit will be completed on 7th September.	No further action.
7) Consent Patient feedback received and observation on the day of inspection indicated that patients are asked to complete consent forms during the information giving appointment. This was considered to provide insufficient time for the person(s) giving consent to reflect on their decision or discuss the decision further as a couple (CoP Guidance 5.6).	The centre should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions **before** obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance. This recommendation should be implemented by	We believe that all our patients are happy with the way we provide a personal one to one induction of the consent forms with a nurse. We provide a 1 hour slot with a nurse to talk through the complex consent forms and provide an opportunity for questions and answers. If the couple require some time alone then we	The Inspector acknowledges the PR's response. In consideration of the fact that the comments in the report resulted from patient feedback the inspector encourages the centre to monitor patients feedback regarding the completion of consent forms in particular the time that couples have to consider, discuss and reflect on their decisions.

	3 September 2012 and the lead inspector notified of the actions taken.	will leave them in the room and if the couple wish to consider the consent overnight then this will of course be granted. This process unsures consents are compliant and compatible and we believe a better option than the mass completion of forms by patients all attending a meeting at other centres.	
8) Provision of information to the HFEA At the time of the inspection there were a significant amount of intention to treat forms outstanding, in addition to late submission of treatment forms and three missing donor registration forms (General Direction 0008)	The PR should review the mechanism in place to ensure that ITT (intention to treat), treatment and donor registration forms are submitted to the Register within the timescales required by General Direction 0008. This recommendation should be implemented by 3 September 2012 and the changes made notified to the lead inspector.	we were aware of the issue of the ITT forms prior to the inspection and following an investigation into the complexities of the system we rectified the process. In June we received a green light on the RBAT system for ITT forms returns.	The inspector notes that on 6 September 2012 the registry team at the HFEA reported significant improvement in the centres registry submissions. The Inspector acknowledges the improvements. The provision of information to the HFEA will continue to be monitored.

9) The documentation of WoC assessment During an audit of six patient records on the day of inspection it was noted that in one instance treatment had been provided without the WoC documentation being signed by the clinician. (SLC T56 and T15(a)	The PR should audit patien records for the accurate completion and documentation of WoC documentation prior to patients being offered treatment (SLC T56 and T15(a)). This recommendation should be implemented by 3 September 2012 and the lead inspector notified of the results of the audit.	We have carried out a Quality Audit for Consents and the welfare of the child assessments. This audit of WOC was carried out 21/8/2011. The results of the audit will be sent prior to the 3/9/2011.	Audit received 6 September 2012 No further action

Additional information from the Person Responsible
Thank you for your commentsd and we look forward to correcting the issues identified and improving our systems even further to ensure 100% compliance. It should be noted that due to technical difficulties experienced by the PR in completing his response to the inspection report the Inspector has, as requested by the PR copied some of the responses directly from an email from the PR. He has confirmed that these responses have been transcribed accurately.

HFEA Executive Licensing Panel Meeting

21 September 2012

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

Minutes – Item 3

Centre 0030 – (Herts and Essex Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Rachel Hopkins, Head of Human Resources Paula Robinson, Head of Business Planning	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, or its predecessor, has held a licence with the HFEA since 1992 and provides a full range of fertility services.

2. The Panel noted that the centre provided 1424 cycles of treatment (excluding partner intrauterine insemination cycles) in the 12 months to April 2012 and is a large centre.

3. The Panel noted that, for April 2011 to March 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20% and this represents performance that is not likely to be statistically different from the 15% live birth rate target.

4. The Panel noted the increase reported in clinical multiple pregnancy rates from 2010/11 to 2011/12. Since the report does not establish that this increase is statistically significant, the Panel agreed that a review of the centre's strategy may help to determine whether the centre is on course to meet the more stringent target that comes into force in October 2012.

5. The Panel noted that, at the time of the inspection, there were recommendations for improvement in relation to one critical area of non-compliance, three major and nine other areas of non-compliance or areas that require improvement.

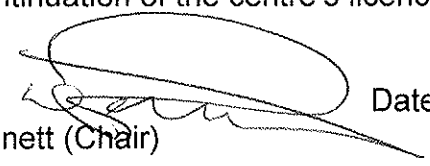
6. The Panel noted that since the inspection, the Person Responsible (PR) has given a commitment to fully implement all of the recommendations made in the report and has submitted all of the requested documentation.

7. The Panel noted that two of the major areas of non-compliance were upgraded from 'other' because they were outstanding from the last inspection in July 2010. The Panel urged the PR to deal with reported non-compliances and recommendations within the described timeframes in future.

8. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

9. The Panel agreed to the Inspectorate's recommendation for the continuation of the centre's licence with no additional conditions.

Signed:  Date: 20th 2012

Mark Bennett (Chair)