Interim Licensing Report

Centre name: Complete Fertility Centre Southampton
Centre number: 0307
Date licence issued: 1 November 2011
Licence expiry date: 31 October 2015
Additional conditions applied to this licence: None
Date of inspection: 12 June 2013
Inspectors: Andrew Leonard (Lead); Janet Kirkland; Lisa Beaumont (observing)
Date of Executive Licensing Panel: 16 August 2013

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 (ELP) 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 progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

The ELP is asked to note that recommendations for improvement were made in relation to two 'major' and eight 'other' area(s) of non-compliance.

Evidence provided by the PR in response to the inspection report indicates that two 'major' recommendations and two 'other' recommendations have been fully implemented.

'Major' areas of non compliance:

1. The PR should provide the HFEA with an update on the number of patients for whom gametes remain in store without effective consent and a plan, with timescales for implementation, documenting the centre's intended actions regarding those samples.
2. The PR should immediately ensure that appropriate actions are planned and implemented to prevent the inadvertent release to unlicensed persons of patient identifying and medical treatment information during conversations at the reception desk.

'Other' areas of practice that require improvement:

5. The PR should ensure that appropriate corrective actions are always included in audit reports to address non-conformances documented in those audits.
8. The PR should take immediate action to ensure that all witnessing checks are appropriately documented in patient records.

The PR in his response to the report committed to implement, and provided evidence of progressing but not yet completely implementing, these remaining eight 'other' recommendations:

3. The PR should ensure that the planned corrections and revisions to patient information are completed and that a summary of the changes made is provided to the HFEA.
4. The PR should ensure that in cases where multiple embryos have been transferred to a patient who meets elective single embryo transfer (eSET) criteria, the reasons for transferring more than one embryo are documented in the patient's notes. Within three months of this change in practice, the PR should conduct an audit of patient records to evaluate whether the change has been implemented effectively. A report of the audit findings should be submitted to the HFEA.
6. The PR should provide the HFEA with an audit schedule documenting all critical activities to be audited with anticipated completion dates. The PR should thereafter provide monthly updates to the HFEA on the audit schedule's progress.
7. To increase the robustness of the risk control measures at egg collection, the PR should ensure that checks that critical work areas are cleared of all tubes and dishes before and after each egg collection are, when completed, documented in the patient records. An audit of the completion and documentation of the checks should be performed for a sample of records in the three months after

implementation and a report of the audit should be provided to the HFEA.

9. The PR should ensure that all relevant SOPs are reviewed to verify that they detail the specifications for all critical materials and reagents used in the procedures they describe. A report of this review including a description of the actions taken should be provided to the HFEA.
10. The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA. A report of the audit findings should be submitted to the HFEA. Three months after the implementation of corrective actions, the centre should audit a random sample of ten patient records to ensure that the consent to disclosure decisions have been correctly transferred to the HFEA register. This audit should be submitted to the HFEA.

These remaining recommendations should be implemented within the timescales specified in the report and evidence of this provided to the Lead Inspector.

Information about the centre

The Complete Fertility Centre is located in the Princess Anne Hospital, Southampton. The centre has held a licence with the HFEA since 1 November 2008 to provide basic treatment and storage services.

The centre underwent refurbishment of their premises in 2010 to enable it to offer a full range of treatment and storage activities. An application to vary the licence to reflect this was granted in December 2010 and the centre started to provide a full range of fertility services in early spring 2011.

The centre provided 484 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2013. In relation to activity levels this is a small centre. It is noted that activity in the previous year to 30 April 2012 comprised 313 cycles. Thus activity in the year to 30 April 2013 has increased approximately 54% compared to the previous year.

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 held register data for the year ending 31 January 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception: Clinical pregnancy rates following ICSI in patients aged <38 years are below the national average.

In 2012 the centre reported 47 cycles of partner insemination with 8 pregnancies, a success rate in line with national averages.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

The centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups between 1 April 2010 and 31 March 2011 has not been calculated because activity at the centre during this period was too low for the data to have statistical significance.

Between 01 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represented performance that was not likely to be statistically different to the 15% live birth rate target for this time period.

[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 toa MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Between 1 January 2012 and 31 December 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. The reduction in the multiple pregnancy rate in 2012 relative to that between 01 April 2011 and 30 September 2012, suggests the centre is being proactive and effective in adapting their multiple birth minimisation strategy to meet the HFEA's multiple birth rate target. A detailed review of the multiple births minimisation strategy was also provided by the centre in evidence of this.

Witnessing

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; fertilisation checks; thawing of gametes; sperm preparation; preparation for embryo transfer. The procedures were, with one exception, witnessed in accordance with HFEA requirements, using an electronic witnessing system, with additional manual witnessing when required. The exception concerned egg collection, when eggs are collected in the procedure room into tubes which are not labelled and are then transferred into an unlabelled dish for microscopic examination (SLC T71; T101). At this point the eggs are transferred into an appropriately labelled and witnessed egg culture dish. Witnessing and labelling practices at egg collection have been risk assessed and found to be safe. The risk assessment was provided to the inspection team and was considered generally appropriate except that it does not include that the risk control steps should be documented in the relevant patient record each time they are completed (Recommendation 7).

The inspection team reviewed the centre's report of an audit of witnessing documentation in 50 patient records and also reviewed five sets of patient records. The team concluded that records of manual and electronic witnessing are maintained in a generally compliant manner, the only exception being that the times at which three manual witnessing checks were performed were not documented (Recommendation 8).

Consent: Disclosure to researchers

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 11 patients and their partners were reviewed in the course of the inspection. The consents were completed and reported accurately to the HFEA with the exception of the consents from one partner, which were present in the records but had not been reported to the HFEA (Recommendation 10).

Consent: To the storage of cryopreserved material

The storage periods for three sets of embryos recorded on the centre's database were cross checked against the consent given by the gamete providers. In each case, the embryos were within their consented storage period and the period recorded in the database concurred with that recorded on the consent forms in the patient records.

Further review of the centre's storage database indicated that gametes and embryos in store at the centre on the day of the inspection are within their consented storage periods except for cryopreserved sperm from three providers for which the written effective consent for storage had expired. The inspection team considered this was not due to a failure of the centre's bring-forward system, as the centre has documented adequate attempts to contact the gamete providers and verbal consent to continued storage given by the providers in telephone conversations. Rather, the providers have promised to send completed consent forms to the centre but have not done so (Recommendation 1).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a 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. The PR advised that the centre was now at the activity level for which it was initially staffed and that staffing resources will be reviewed if any further increases in treatment activity are planned.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. The centre's recent patient satisfaction survey was also reviewed. A further 44 patients provided feedback directly to the HFEA in the time since the inspection in April 2011.

Patient feedback was generally positive: for example 27 of the 44 respondents providing written feedback to the HFEA commented that they had compliments about the care that they received.

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

- has professional, caring and friendly staff who are committed to patient care;
- 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.

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 us.

Compliance with HFEA standard licence conditions

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

- The recently performed patient satisfaction survey reported that patient identifying and medical treatment information discussed at the reception desk could be easily overheard by patients in the waiting area (Recommendation 2).
- Corrections and revisions to patient information in response to the findings of a compliance audit have not been implemented. The PR advised that these actions will be completed by 1 August 2013 (Recommendation 3).
- In a sample of patient records, there was no clear explanation of the reasons for transferring more than one embryo in cases where eSET criteria were met (Recommendation 4).
- Reports of the audits of the selection and recruitment of sperm donors and egg sharers have been documented but the reports do not document appropriate corrective actions to address non-conformances (Recommendation 5).
- The centre has not in the last two years audited how far some procedures for processing (e.g. sperm preparation; egg collection; ICSI; cryopreservation; embryo transfer) comply with the approved protocols, the regulatory requirements and quality indicators (Recommendation 6).
- The centre's SOPs do not all detail the specifications for critical materials and reagents used in the procedures. The laboratory manager discussed the centre's on-going actions to correct this issue (Recommendation 9).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in April 2011, no recommendations for improvement were made in relation to 'critical' or 'major' areas of non-compliance. Recommendations were though made concerning five 'other' areas of non-compliance. The PR provided information and evidence that all of these recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

HFEA held register data for the year ending 31 January 2013 show the centre's clinical pregnancy rates following ICSI in patients aged <38 years are below the national average. During discussions on inspection, the PR and laboratory manager provided evidence of on-going corrective actions and a commitment to keep success rates under review and to take further action if necessary.

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.

The HFEA register team have reviewed the centre's EDI data submissions and have no significant regulatory concerns regarding them.

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 PR’s statement
None found			

‘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 PR’s statement
1. On the day of the inspection, the centre did not have written effective consent for the storage of cryopreserved gametes from three providers (HF&E Act 1990 (as amended), Schedule 3, 8.1).	The PR should note that storage consent must be appropriately documented on HFEA consent forms for it to be effective and that it is unlawful to continue to store gametes when consent to storage is not present. The PR is reminded of guidance issued in Chairs Letter (03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material and actions to take should there be a possibility of legal challenge to the disposal. The PR should provide the HFEA with an update on the number of patients for whom gametes remain in store without effective consent and a plan,	I note that the response of the lab manager was considered to fully address this issue and that no further actions are required.	24 June 2013: The laboratory manager emailed to confirm that the three gamete providers have consented to the withdrawal of their gametes from storage and the samples have since been allowed to perish. No further actions are required

	with timescales for implementation, documenting the centre's intended actions regarding those samples. This plan should be provided by 12 July 2013. The PR should thereafter provide monthly updates to the HFEA on progress in implementing the proposed actions.		
2. The recently performed patient satisfaction survey reported that patient identifying and medical treatment information discussed at the reception desk could be easily overheard by patients in the waiting area (SLC T43).	The PR should immediately ensure that appropriate actions are planned and implemented to prevent the inadvertent release to unlicensed persons of patient identifying and medical treatment information during conversations at the reception desk. The actions taken should be provided to the HFEA by 12 September 2013, with monthly updates thereafter regarding their implementation.	Following receipt of the interim report we took immediate and extensive action to address this. We have invited the Estates Department to provide options for building works necessary to increase privacy in the waiting room. In the meantime we have taken immediate interim measures by closing the reception desk and requiring patients to enter a separate room to discuss appointments etc. While these are addressing the issue of patients being overheard, they are causing considerable inconvenience, and we are looking at other interim	29 July 2013: The PR's response indicates that the centre has taken actions to address concerns regarding patient confidentiality. No further actions are required. The Executive will liaise with the centre going forward to ensure compliance if the centre make further changes to improve the reception area.

		options which are less disruptive to the work of the unit. We will continue to liase with the HFEA to ensure these interim arrangements are deemed compliant.	

‘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 PR’s statement
3. Corrections and revisions to patient information in response to the findings of the centre’s compliance audit have not been implemented (SLC T36).	The PR should ensure that the planned corrections and revisions to patient information are completed. A summary of the changes made should be provided to the HFEA by 12 September 2013.	The planned corrections and revisions to patient information are now been completed. A summary will be sent well before the requested date.	29 July 2013: The PR’s response indicates that actions to address this issue are being implemented. The PR has committed to advise the Executive when these actions are completed.
4. In a sample of patient records, there was no clear explanation of the reasons for transferring more than one embryo in cases where eSET criteria were met (General Direction 0003).	The PR should immediately ensure that in cases where multiple embryos have been transferred to a patient who meets eSET criteria, a clear explanation of the reasons for transferring more than one embryo is documented in the patient's notes. Confirmation of this change in practice should be provided to the HFEA when this report is returned with the PR's feedback. Within three months of the change, the PR should conduct an audit of patient records to evaluate whether the change has been	We now require the doctor performing the ET to provide a clear explaination of the reasons for transferring more than one embryo. The new procedure has been implemented and will be subject to audit prior 12 September. Any further corrective actions thus identified will be reported as will the timescales for their implementation. In the meantime, our revised 'Multiple Birth Minimisation Strategy' document is attached.	29 July 2013: The PR’s response indicates that actions to address this issue have been implemented, except for the audit to ensure the corrective actions have embedded. The PR has committed to advise the Executive when this further action is completed.

	implemented effectively. A summary report of the audit findings including any further corrective actions and timescales for their implementation should be submitted to the HFEA by 12 September 2013.		
5. The findings of the audits of the selection and recruitment of sperm donors and egg sharers have been documented but appropriate corrective actions to address the non-conformances are not documented (SLC T36)	The PR should ensure that appropriate corrective actions are included in audit reports to address non-conformances. The reports of the audits of the selection and recruitment of sperm donors and egg sharers should be redrafted to include appropriate corrective actions and should be provided to the HFEA by 12 September 2013	This point too has been subject to immediate attention, and the reports of these audits have been redrafted to include the appropriate corrective actions. The revised Egg Share Program Audit document is attached, ahead of the requested deadline of September 12th 2013	29 July 2013: The PR's response indicates that actions to address this issue have been implemented. No further actions are required.
6. The centre has not in the last two years audited how far some procedures for processing (e.g. sperm preparation; egg collection; ICSI; cryopreservation; embryo transfer) comply with the approved protocols, the regulatory requirements and quality indicators (SLC T36).	The PR should provide the HFEA by 12 September 2013 with an audit schedule documenting all critical activities to be audited, with anticipated completion dates. The PR should thereafter provide monthly updates to the HFEA on the audit schedule's progress until these areas of practice have been audited. It is recommended that audits are	We have fully revised and expanded our audit schedule which documents all critical activitie to be audited, with anticipated completion dates. These will indeed be prioritised on the basis of risk. We attach the revised audit schedule ('Audit Schedule Complete').	29 July 2013: The PR's response indicates that actions to address this issue have been implemented. The revised audit schedule was considered appropriate. Some of the procedures of note have been audited recently, while others will be audited within a reasonable time period. The Executive will continue to follow up on this

	prioritised on the basis of risk.		issue through the monthly audit progress reports from the centre.
7. Eggs are collected into tubes which are not labelled and no witnessing is performed of the transfer of eggs from these tubes into a dish for microscopic examination (SLC T71; T101). These practices have been risk assessed. The inspection team noted that the key risk control checks by two staff members, that the critical work areas are clear of tubes and dishes before and after egg collection, are not documented in the patient records.	The inspection team considered the risk assessment provided good evidence that labelling and witnessing practices at egg collection are safe. To increase the robustness of the risk control measures however, the inspection team recommends that checks that critical work areas are cleared of all tubes and dishes before and after each egg collection are, when completed, documented in the patients records. This action should be implemented by 12 September 2013. An audit of the completion and documentation of the checks should be performed for a sample of records in the three months after implementation. A report of the audit should be provided to the Lead Inspector by 12 December 2013	We have immediately implemented the approprate change in procedures to address this. We attach the revised Embryology worksheet ("Revised Embryology Record Complete') which has been adapted to require appropriate sign off for these steps. An audit of the completion and documentation of the checks will be performed on a sample of records 3 months after implementation, and a report of this audit will be provided to the Lead Inspector by 12 december 2013.	29 July 2013: The PR's response indicates that actions to address this issue have been implemented, except for the audit to ensure the corrective actions have embedded. The PR has committed to advise the Executive when this further action is completed.
8. The times of three witnessing checks were not documented in the patient	The PR should take immediate action to ensure that all witnessing checks are	We have discussed this point internally and reminded members of the team of the	29 July 2013: The PR's response indicates that actions to address this issue

records (SLC T71).	appropriately recorded in each patient's record. The HFEA should be advised by 12 September 2013 of the measures taken to ensure that this occurs.	importance of recording all witnessing checks in the patient record; including times. In order to ensure that this occurs, this procedure will be subject to audit prior to the 12th September.	have been implemented. No further actions are required.
9. The centre's SOPs do not all detail the specifications for critical materials and reagents used in the procedures (SLC T31).	The PR should ensure that all relevant SOPs are reviewed to verify that they detail the specifications for all critical materials and reagents used in the procedures they describe. A report of this review including a description of the actions taken should be provided to the HFEA by 12 September 2013.	We have reviewed all relevant SOPS and in order to address the point raised, we are creating a new document which lists the specifications for critical materials and reagents used. Each is being given a code which will be referred to in the individual SOPs. We will provide this list and example supporting SOPs by the stated requested date.	29 July 2013: The PR's response indicates that actions to address this issue are being implemented. The PR has committed to advise the Executive when these further actions are implemented.
10. The records of consent to disclosure to researchers given by 10 patients and their partners were reviewed in the course of the inspection. One set of partner consents were present in the records but had not been reported to the HFEA.	The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA. A report of the audit findings, including corrective actions with timescales for implementation, should be submitted to the HFEA by 12 September 2013. Three months after the implementation of corrective	We have indeed audited the procedures for submitting patient's consent. This is a generci audit which also addresses the specific issue of consent to research. We have attached a copy of this audit. ('Consent to Disclosure Audit Complete') A number of corrective actions have been identified and the time scale for implementing these is also	29 July 2013: The PR's response indicates that actions to address this issue are being implemented. The audit report with corrective actions was reviewed and was considered appropriate. The PR has committed to advise the Executive when these further actions are implemented.

	actions the centre should audit a random sample of ten patient records to ensure that the consent to disclosure decisions have been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA by 12 December 2013, for cross reference against the records held by the HFEA.	already given, ahead of the requested deadline of 12 september 2013.	

Additional information from the Person Responsible
We are grateful for the many positive comments made in the report regarding the performance of our unit. The non-compliances which were identified from the unannounced inspection have provided further impetus to ensuring we have systems in place to ensure implementation and reaudit of corrective actions. With the return of our Quality Manager, who had been absent for visa reasons prior to and at the time of the inspection, we are now in a position to address the issues raised with the necessary urgency and effectiveness. Indeed, a number of the actions required prior to 12th September have already been effected, and a number of these are evidenced in the attachments accompanying this form. With regard to our clinical outcomes, we appreciate the recognition of the work we have done achieve multiple preganancy rates at around 10%, which is well below the national average. Despite this, we have maintained ongoing clinical pregnancy rates within the national average, and these continue to rise this year. We will continue to monitor clinical outcomes closely, but anticipate that the current trend to rising ongoing pregnancy rates will continue and soon be reflected in the HFEA figures.

HFEA Executive Licensing Panel Meeting

16 August 2013

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

Minutes – Item 5

Centre 0307 – (Complete Fertility Centre Southampton) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair)	Rebecca Loveys
Jasper Squire – Computer Programmer	Observing:
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that this is a small centre which provides a full range of fertility services, and has been licensed since 2008.

2. The Panel noted that the centre is currently on a four year licence due to expire in October 2015.

3. The Panel noted that in the 12 months to 30 April 2013, the centre provided 484 cycles of treatment (excluding partner intrauterine insemination), and that the centre's activity has increased approximately 54% compared to the 12 months to 30 April 2012.

4. The Panel noted that for the year ending 31 January 2013 the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the exception of clinical pregnancy rates following ICSI in patients under 38, which are below the national average.

5. The Panel noted that for the time period 1 April 2011 to 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%, which represents performance that is not likely to be statistically different from the 15% live birth rate target for this period.

6. The Panel noted that, at the time of inspection, one major and eight other areas of non-compliance were identified.

Decision

7. The Panel had regard to its decision tree. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

Signed:  Date: 21 August 2013

Juliet Tizzard (Chair)