Inspection Report

Date of Inspection: 27th March 2012
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 8 hours
Inspectors: Janet Kirkland MacHattie
Vicki Lamb

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 18th May 2010 and 27th March 2012.

Date of Executive Licensing Panel: 13 July 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 interim 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 Licence Committee/ Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Oxford Fertility Unit
Centre Number	0035
Licence Number	L0035/12/c
Centre Address	Institute for Reproductive Sciences, Oxford Business Park North, Oxford, OX4 2HW
Person Responsible	Mr Tim Child
Licence Holder	Mrs Janet Talbot
Date Licence issued	21st September 2009
Licence expiry date	30th September 2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Oxford Fertility Unit (OFU) was first established as an HFEA licensed clinic in 1992 and re-located to purpose-built premises in 2009. These new premises were inspected by the HFEA on 25 August 2009 and granted a treatment and storage licence on 21st September 2009.

Centre 0035 provides a full range of licensed treatments to self-funded and NHS patients including preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD). The centre is open 7 days a week, 08.00 to 16.30 Monday to Friday and 08.00 to 12.00 on Saturday and Sunday.

The Person Responsible (PR) is accredited with the General Medical Council (GMC) as both Consultant Obstetrician & Gynaecologist and a sub-specialist in reproductive medicine. The PR has completed the HFEA PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 February 2011 - 31 January 2012
In vitro fertilisation including fresh and frozen embryo replacement cycles (IVF)	1110
Intracytoplasmic sperm injection including fresh and frozen embryo replacement cycles (ICSI)	1088
Gamete intrafallopian transfer (GIFT)	0
Donor insemination (DI)	41
Egg share provider (sharer)	16
Egg share recipient	16
Egg donation (non-egg share)	4

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period Nov 2010 – Oct 2011show the centres success rates are in line with national averages with the following exceptions:
The clinical pregnancy rate (CPR) for IVF patients aged 16-37 is above the national average.
The clinical pregnancy rate (CPR) for FER patients aged 16-37 is above the national average.

*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 – post 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 draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that there are a number of areas of practice that require improvement, two major areas of non-compliance and one other area of non-compliance or area of poor practice.

Since the inspection visit on 27 March 2012 the PR has given a commitment to fully implement all of the following recommendations made in the report:

Major areas of non compliance

- The Person Responsible (PR) should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by Licence Condition T21.
- The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue.

Other areas of practice that require improvement

- The PR to review the systems and processes regarding the recording of consent to disclosure and to implement corrective actions to ensure correct recording of consent and transfer of data to the HFEA registry team. The centre team should audit all of their consent forms against the submissions to the HFEA and make any relevant corrections.

Recommendation to the Executive Licensing Panel.

The inspection team considers that, overall there is sufficient information available to recommend the continuation of this centre's licence without additional conditions. In making this recommendation it is noted that the PR has responded to all of the recommendations made in this inspection report.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed Treatment Plans:** Both self funding and NHS funded patients are provided with services at the centre. Self funding patients are provided with a price list on which the cost of the treatment package they require is highlighted. In most cases the package price covers all costs and there are few additional costs which might arise. Those that may are also provided on the price list and are discussed with the patient. The price list is also available on the centre's website. **Legal parenthood** This theme was covered at the last inspection. The issue of legal parenthood is discussed at initial consultation and followed up at the consent appointment when the necessary documentation is signed. Centre staff interviewed had a good understanding of the issues surrounding legal parenthood. Evidence of the appropriate completion of consents to legal parenthood were observed in a set of patient notes.
What they could do better. Nothing noted at the time of the inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure to researchers** This was discussed at the previous inspection when it was considered that consenting practices with respect to the disclosure of registry information to researchers were compliant. The centre has established quality indicators and have performed an audit in relation to consent. Findings have been recorded and corrective actions documented and implemented (Standard Licence Condition T35 T36). During the inspection an audit of eight sets of patient medical records showed that the appropriate HFEA consent to disclosure had been completed in all sets of records.

Consent to treatment
Six records were audited for consent to treatment. All consents were found to be in place.

Consent to storage
The laboratory manager confirmed that the centre had written effective consent for all cryopreserved gametes and embryos in store. A list was provided for the inspection team and all stored material was seen to be in date.

Patients sign a consent form which includes a section on the "cooling off period". In addition to this they are sent an annual storage form to confirm their wishes for the gametes/embryos in storage.

The laboratory manager demonstrated a good understanding of the limitations of the cooling off period.

What they could do better

Consent to disclosure to researchers
The audit of patient files highlighted a discrepancy in the reporting of consent to the HFEA in three of the eight records examined.

Multiple births

For the year April 2010 to March 2011 the centres multiple clinical pregnancy rate was 17%. This represents performance likely to be significantly below the target for 2010/11.

On-going monitoring of the centres multiple clinical pregnancy rate from April 2011 briefly showed performance that, if it had continued on this trajectory, would have made it unlikely that the centre would meet the 2011/12 target. Monitoring of performance over the last 6 months suggests that the centre has been proactive in implementing changes to their practices and if performance continues on the current trajectory they will be likely to meet the 2011/12 target.

What the centre does well.

The PR has provided sufficient evidence to demonstrate compliance with HFEA Directions 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

What they could do better.

Nothing noted at the time of the inspection

Validation of critical equipment and processes

What the centre does well

All equipment and processes have been validated.

New equipment and processes will be validated before being brought into clinical use (Standard Licence Condition T24, T25, T72 and T73).

The Standard Operating Procedure (SOP) for validation includes the necessity to provide documented evidence of the revalidation of equipment after repair.

A comprehensive validation for an incubator was seen on inspection.

CE marked consumables are used for the procurement of gametes and/or embryos.

What they could do better

Nothing noted at the time of the inspection

Witnessing

What the centre does well

The centre uses an electronic witnessing system and /or manual witnessing, at all critical points of the clinical and laboratory processes (Licence Condition T71). All witnessing is carried out contemporaneously (Licence Condition T71).

A record of electronic witnessing is printed and placed in each patient record after treatment (CoP Guidance 18.7). Five patient files were reviewed by the inspection team and all witnessing steps were seen to have been documented.

A quality indicator for witnessing has been established requiring 100% of witnessing steps to be correctly recorded in patient records.

The Centre audited its witnessing procedures in January 2012.

The laboratory manager informed the inspection team that staff were trained in witnessing procedures and have had their competence to perform witnessing assessed at induction and then annually thereafter.

What they could do better.

Nothing noted at the time of the inspection.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The centre has established quality indicators and has audited in relation to selection and recruitment of donors .Findings have been recorded and corrective actions documented and implemented (SLC T35 T 36) An SOP is in place for the process to be followed when selecting and recruiting donors. Key staff are involved in the donation programme and a competency framework relevant to donation was provided for the inspection team. . The Quality Manager informed the inspection team that all procedures have been audited against regulatory requirements. A list of quality indicators including selection and recruitment of donors was provided for the inspection team. Five sets of donor files were reviewed at inspection and screening as required was seen to have been carried out. Screening samples are analysed in a CPA accredited laboratory. The senior nurse informed the inspection team that the centre are aware of the changes in donor reimbursement effective from April 1st 2012
What they could do better. Nothing noted at the time of the inspection

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. Not relevant at this inspection
What they could do better. Not relevant at this inspection

Embryo testing (if applicable)
What the centre does well. The centre has established quality indicators and has audited in relation to embryo testing. There is an SOP for embryo biopsy. There are two biopsy practitioners at the centre in addition to a trainee.

The centre have adopted well established embryo biopsy procedures. Quality Indicators relevant to biopsy procedures were seen at the inspection in addition to an audit of biopsy results. The competence of biopsy practitioners is assessed via an “exam” and regular audits.
What they could do better. The laboratory carrying out the PGS/and or PGD testing is not yet accredited by CPA. The inspection team were informed that an application for accreditation has been submitted. In correspondence with the PR post inspection he indicated that they would expect the laboratory to achieve CPA accreditation by the end of the year. This non-compliance was highlighted at the time of the last inspection and the PR reported that it was expected that the laboratory would have achieved accreditation by the end of 2010. The PR has kept the HFEA fully informed of delays in the testing laboratory achieving accreditation which have been beyond the influence of the centre.

2. Changes / improvements since the previous inspection on 18th May 2010.

Area for improvement	Action required	Action taken as evidenced during this inspection
According to HFEA registry data, the multiple pregnancy rate at the centre in all patients increased from 24 to 27% between 2008 and 2009. It is possible that the 27% multiple pregnancy rate will lead to a multiple birth rate above the 24% target for 2009, non-compliant with Direction 0003 (version 1).	The inspectorate recommends that the PR continues to monitor the centre's MBMS and how it is applied, as planned, to ensure that the 20% MBR target for 2010/2011 is achieved. This action will be monitored at the time of the next inspection	For the year April 2010 to March 2011 the centres multiple clinical pregnancy rate was 17%. This was significantly below the target for 2010/11. On-going monitoring of the centres multiple clinical pregnancy rate from April 2011 briefly showed performance that was a cause of concern: if performance had continued on this trajectory it would have been unlikely that the centre would meet the 2011/12 target. Monitoring of performance over the last 6 months suggests that the centre has been proactive in implementing changes to their practices and if performance continues on the current trajectory they will be likely to meet the 2011/12 target. **No further action**
Competency assessments have been performed in multiple activities, however to ensure full compliance with Licence Conditions T12 and T15a, competency assessments need to be completed and documented for all relevant staff for witnessing, donor selection and recruitment, cryostorage	The PR should ensure the competency assessment programme is completed, as required by Licence Conditions T12 and T15a. This action should be completed by 1 October 2010.	This was discussed in some detail with the PR. He confirmed that he is confident of the competency of all staff. All new staff receive a two week induction in addition to customised training in the relevant disciplines. Annual competency checks are performed for all staff.

Area for improvement	Action required	Action taken as evidenced during this inspection
and for the submission of data to the HFEA.		**No further action required.**
In the SAQ, the PR indicated that the centre was not fully compliant with Licence Condition T21; i.e. with the requirement that all diagnostic services used in support of patient treatment are appropriately accredited	The PR should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by Licence Condition T21. This should be accomplished by 1 October 2010.	The PR informed the inspection team that the appropriate application had been submitted for accreditation of the PGD/PGS laboratory **Further action required.** **See major area of non-compliance.**
On inspection it was observed that health and safety signage was absent in several areas. Thus it is questionable that the PR has complied with his responsibilities under Licence Condition T9b, i.e. that the premises are suitable for the licensed activities which are undertaken there.	The PR said that health and safety management had recently changed, and an external consultancy would now provide a Health and Safety service which would include a review of signage at the centre. This review needs to be performed, to ensure that appropriate health and safety signage is displayed for risk control purposes within the centre. It should be completed by 1 September 2010	Health and Safety signage was seen to be in place in the areas identified by the PR. **No further action required**
The SAQ indicated and evidenced on inspection confirmed that third party agreements (TPAs) were not in place with all suppliers required by Licence Condition T111. Third parties have also not been evaluated for their compliance with HFEA requirements, as required by Licence Condition T112	The PR should ensure the final two TPAs are developed to comply with Licence Condition T111. The PR should also ensure that all service providers are regularly evaluated for their compliance with HFEA Licence Conditions and other requirements, to comply with Licence condition T112. These actions should be completed by the 1O October 2010.	The PR and Quality Manager assured the inspection team that all third party agreements were in place and had been audited against compliance. A comprehensive list of third party agreements was provided for the inspection team. **No further action required**
Given the QI audits performed, the centre needs to develop quality indicator monitoring and audit for	The PR should ensure these QI audits are developed to comply with Licence	The Quality Manager assured the inspection team that quality indicator monitoring

Area for improvement	Action required	Action taken as evidenced during this inspection
HFEA data submission, counselling provision and patient confidentiality and privacy, to be compliant with Licence Condition T35.	Condition T35. The PR should also ensure that the monitoring mechanisms, audit frequencies and responsibilities for all quality indicators, as well as associated quality objectives, are documented in procedures, to comply with CoP guidance 23.19 – 23.22. This action should be taken by 1 September 2010.	for HFEA data submission, counselling provision and patient confidentiality and privacy had been developed and audits had been performed. A list of Quality Indicators was provided for the inspection team. An audit report was seen to include: non-conformities, corrective action, preventive action, date of implementation, manager responsible and frequency of follow up **No further action required**
All equipment failures are brought to the LM's attention and after repair, equipment is re-validated before re-entering service. These common practices are not documented in procedures, non-compliant with Licence Conditions T25 and T27	The PR should ensure the update of procedures to include the actions to be taken in response to suspicion of failure. The equipment maintenance and repair procedure should detail that all equipment returned to the centre after repair is revalidated before being used in licensed activities, to ensure compliance with Licence Condition T25. These procedural changes should be made by 1 September 2010	The SOP includes the revalidation of equipment after repair. **No further action required**
HFEA Finance reported before inspection that invoices in the year to 6th March 2010 had been paid in an average of 31 days (range 8 – 53 days). Since the invoice in July 2009 which took 53 days to be paid, the centre has taken under 37 days to pay each invoice.	The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue. The PR is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to	**Further action required** **(see major area of non-compliance)**

Area for improvement	Action required	Action taken as evidenced during this inspection
	attempt to meet the 28 day payment deadline.	

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
In the SAQ the PR indicated that the centre was unlikely to meet the current multiple birth rate target.	See comment in the body of the report	**No further action** .
In the SAQ the PR indicated that the centre were not compliant with T21, that the laboratory that carries out PGS and/or PGD is accredited by Clinical Pathology Accreditation (CPA)UK Ltd or an alternative body accrediting to an equivalent standard.	Licence Condition T21 requires that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited. This has been discussed with the PR on previous inspection. The PR and Laboratory Manager informed the inspection team that the application for accreditation had been submitted.	This was highlighted following the previous inspection on 18th May 2010. At that time the PR assured the executive that the laboratory that carries out PGS and/or PGD would achieve CPA accreditation by October 2010. This should be resolved with some urgency. The PR should provide a time line for the expected accreditation prior to the report being considered by The Executive Licensing Panel (ELP on July 17th 2012).He should also consider and inform the executive of what actions he will take should the accreditation not be achieved by December 2012

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
In the SAQ the PR indicated that the centre were no fully compliant with T15(a) that all staff can provide documented evidence of their competence in selecting and recruiting donors.	This was discussed with the senior nurse who demonstrated a competence assessment framework for selecting and recruiting donors. She further explained that there are key staff involved in the donation programme and they assess each others competencies.	The Inspectorate found no evidence that the centre was non-compliant with T15(a). **No further action required**
In the SAQ the PR indicated that the centre were not compliant with T 50f: that prior to the processing of patient gametes or embryos intended for use in treatment or storage the centre perform HTLV-1 antibody testing for patients living in or originating from high incidence areas or with sexual partners originating form those areas or where the donor's parents originate from those areas.	This has been discussed at length on previous inspection. The PR has indicated on the SAQ that they do not perform HTLV-1 testing, however, on discussion with the PR and the senior nurse the inspection team were informed that no patients/donors requiring this screening have been treated . If the case arose and after consultation and discussion with the patient/donor it was assessed that further testing was required it would be performed. It was noted by the inspection team that the check list for donor screening included HTLV 1&2.	: **No further action required**
In the SAQ the PR indicated that the centre were not compliant with T50(g): That in appropriate circumstances the centre carry out additional testing on the	The PR has indicated on the SAQ that in appropriate circumstances the centre do not carry out additional testing on the patients travel and exposure history and	**No further action required**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
patients travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria,CMV,T cruzi)	the characteristics of the tissue or cells donated (eg, Rh D, Malaria,CMV,T cruzi) However, on discussion with the PR and the senior nurse the inspection team were informed that no patients/donors requiring this screening have been treated. If the case arose and after consultation and discussion with the patient/donor it was assessed that further testing was required it would be performed	
In the SAQ the PR indicated that the centre were not compliant with Act Schedule 3A(11)-2006/17/EC,T50(c) that HTLV-1 antibody testing is performed if the gamete provider lives in or originates from high incidence areas or has sexual partners originating from those areas, or if their parents originate from those areas.	This was discussed at length on inspection. The PR explained that that this has not been an issue with patients/donors at the centre but if it was considered that there was a risk to/from the patient/donor then the tests would be performed as required.	**No further action required**
In the SAQ the PR indicated that the centre were not fully compliant with T35: that the centre had established quality indicators for all licensed activities carried out in the course of providing treatment services that do not require a licence.	On inspection the PR and Quality Manager informed the inspection team that they had a robust Quality Management System. A comprehensive list of Quality Indicators was provided for the inspection team in addition to examples of audit and corrective/preventive action reports.	The inspectorate could find no evidence that the centre was non-compliant with Licence Condition T35 **No further action required**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
In the SAQ the PR indicated that the centre were not compliant in that where a third party procure gametes and/or embryos on behalf of the centre, the third party provide a report that complies with T117	The PR informed the inspection team that they do not have third parties who procure gametes and/or embryos on behalf of the centre.	The inspectorate could find no evidence that the centre was non-compliant with Licence Condition T117 **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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct 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 noted at the time of the inspection.			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The laboratory carrying out the PGS/and or PGD testing is not yet accredited by CPA. The inspection team were informed that an application for accreditation has been submitted. In correspondence with the PR post inspection he indicated that they would expect the laboratory to achieve CPA accreditation by the end of the year. Following an inspection on **18th May 2010** it was documented in the report that "The PR should ensure that all diagnostic services used by	The PR should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by Licence Condition. T21. The PR to provide a realistic time line for the expected accreditation prior to the report being considered by The Executive Licensing Panel (ELP) on 29th June 2012.He should also consider and inform the executive of what actions he will take should the laboratory not be CPA	I have been told by the Director of the PGD/S laboratory that CPA accreditation is expected by the end of the year. An external QM is currently working with them in order to achieve this and will be releasing his interim report on June 1st which will be forwarded to myself. The	The PRs response is noted. The PR should keep the HFEA updated of progress in the delivery of accreditations and of any delays that arise.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
the centre are provided by suppliers who are appropriately accredited, as required by Licence Condition T21. This should be accomplished by 1 October 2010" This was considered by the Executive Licensing panel on 12th August 2010.	accredited by December 2012.	PGD/S laboratory currently provide services to 13 UK IVF centres. If accreditation is not looking likely by the end of the year then I will discuss further with the HFEA and consider using a different accredited laboratory.	
The centre have, in the period 2011/2012 taken an average of 88 days to pay their invoices. This is clearly non compliant with Chairs Letter CH(10) which requires that invoices are paid within 28days.	The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue. The PR is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to attempt to pay within the appropriate time scale.	I have indicated to the finance team that all HFEA invoices must be paid within 28 days.	The executive considers this a satisfactory response and will continue to monitor through the compliance cycle.

Other areas of practice that require improvement

Other areas of practice that require 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
Consent to disclosure to researchers: An audit of patient files highlighted a discrepancy in consent in three of the files examined compared to registry data held at the HFEA.	The Person Responsible to review the systems and processes regarding the recording of consent to disclosure and to implement corrective actions to ensure correct recording of consent and transfer of data to the HFEA registry team. The centre team should audit all of their consent forms against the submissions to the HFEA and make any relevant corrections. The Person Responsible should submit an action plan that includes timescales for completing this audit.	An audit has been planned and will be completed, and forwarded to the HFEA, within 12 weeks. This will include the appropriate corrective actions to be undertaken.	The executive considers this is a satisfactory response and will look forward to receiving the audit by June 19th.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

13 July 2012

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

Minutes – Item 1

Centre 0035 – (Oxford Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Danielle Hamm, Senior Policy Manager Dave Moysen, Head of Information	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 had been licensed since 1992 and re-located to purpose-built premises in 2009. The Panel noted these premises were granted licensed in September 2009.

2. The Panel noted that the centre provides a full range of licensed treatments to self-funded and NHS patients, including preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD).

3. The Panel noted the centre reported 1110 cycles of in vitro fertilisation (IVF) and 1088 cycles of intracytoplasmic sperm injection (ICSI), during 1 February 2011 – 31 January 2012.

4. The Panel noted that, on the basis of the IVF/ICSI data held on the HFEA register for November 2010 – October 2011, the centre's success rates are in line with national averages.

5. The Panel noted that the centre had a 17% multiple clinical pregnancy rate during the period of April 2010 to March 2011.

6. The Panel noted that at the time of the inspection, there were two major areas of non-compliance and one other area of non-compliance or poor practice identified by the Inspectorate.

7. The Panel noted that, since the inspection, the Person Responsible (PR) has provided a commitment to fully address the areas of non-compliance identified within the prescribed timescales.

8. The Panel noted that the Inspectorate tabled information regarding CPA accreditation of the laboratory at the centre and clarification on prescribed timescales of when recommendations will be implemented. The Panel agreed to accept this additional information as it helped to clarify when the identified non compliances would be remedied.

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

Decision

10. The Panel noted that the centre had implemented all recommendations from the previous inspection.

11. The Panel agreed with the Inspectorate's recommendations made in the report. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed: Date: 20 July 2012
Mark Bennett (Chair)