Inspection Report

Date of Inspection: 30/04/2013 and 01/05/2013
Purpose of inspection: Renewal of Treatment and Storage (including embryo testing) Licence
Length of inspection: 15.5 hours
Inspectors: Sara Parlett, Paula Nolan, Andrew Leonard, Claude Rennert, Cathy Hodgson and Barbara Lewis

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 27/03/2012 and 05/07/2013.

Date of Executive Licensing Panel: 19/07/2013

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 HF&E Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel (ELP) which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Oxford Fertility Unit
Centre number	0035
Licence number	L/0035/12/d
Centre address	Institute of Reproductive Sciences, Oxford Business Park, North Oxford, Oxfordshire, OX4 2HW
Person Responsible	Mr Tim Child
Licence Holder	Ms Janet Talbot
Date licence issued	01/10/2009
Licence expiry date	30/09/2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

Oxford Fertility Unit (OFU) was first established as an HFEA licensed centre in 1992 and re-located to purpose built premises in 2009. The centre was last inspected in March 2012 and the ELP in July 2012, which reviewed the inspection report, agreed to the continuation of its licence.

The centre provides a full range of licensed treatments to self-funded and NHS patients, including pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS). Five satellite centres feed into OFU, enabling patients to undergo part of their treatment at a centre local to them.

A number of HFEA licensed centres have come together to form a partnership of clinics known as the Academic Reproductive Partnership (ARP). These include OFU, IVF Hammersmith (centre 0078), Glasgow Centre for Reproductive Medicine (centre 0250) and Boston Place (centre 0327).

Activities of the Centre:

Type of treatment	Number of treatment cycles for 01/04/2012 - 31/03/2013
In vitro fertilisation (IVF)	1033
Intracytoplasmic sperm injection (ICSI)	903
Frozen embryo transfer (FET)	358
Donor insemination (DI)	29
Intrauterine insemination (IUI)	No data submitted for 2011 or 2012
Egg share provider (sharer)	15
Egg share recipient	16
Egg donation (non egg share)	2

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	✓ (Licence R0111)

Outcomes*

For IVF/ICSI, HFEA held register data for the period 01/12/2011 – 30/11/2012 show the centre's success rates are in line with national averages.

The centre has not provided IUI pregnancy rate data to the HFEA for 2011 or 2012.

*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

In considering overall compliance, the inspection team considers that it has sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the Person Responsible (PR) is suitable and he has discharged his duty under Section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The ELP is asked to note that at the time of the inspection there were recommendations for improvement in relation to two 'major' areas of non-compliance and eleven 'other' areas of non-compliance or areas of poor practice. Since the inspection visit the centre has provided evidence that the following recommendations have been fully implemented:

'Other' areas of practice that require improvement

- The PR should ensure that all witness checks are recorded at the time of the procedure.
- The PR should ensure that donors of gametes and embryos are screened in accordance with current professional guidance produced by the relevant professional bodies.
- The PR should ensure that for all established quality indicators (QIs), the frequency of audit/review and the threshold for corrective action are documented.
- The PR should consider the risks of not labelling the tubes used during egg collection.
- The PR should submit IUI annual returns for 2011 and 2012, and the written agreement with its newest satellite provider. The PR should review the centre's processes for ensuring submission of information required by General Directions within the timescales specified.

The PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance

- The PR should ensure that the traceability procedures for recording consumables/reagents in use in the laboratory are effective.
- The PR should keep the Executive informed on the progress of the testing laboratory towards Clinical Pathology Accreditation UK Ltd (CPA) accreditation. If CPA accreditation is not achieved by December 2013, the PR should assess whether this laboratory should continue to be used for diagnostic analysis.

'Other' areas of practice that require improvement

- The PR should revise the third party agreement (TPA) with the genetic testing laboratory. The PR should also review any other TPAs with third parties that provide test/diagnostic results to the centre and revise if necessary.
- The PR should ensure that the counsellor can provide evidence of full equivalence to accreditation by the British Infertility Counselling Association (BICA).

- The PR should review and revise the areas of concern in the centre's patient information noted by the inspection team.
- The PR should review and revise the centre's research and training standard operating procedure (SOP).
- The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframes required.
- The PR should ensure that consent to disclosure of identifying information to researchers is submitted accurately to the HFEA.

Recommendation to the Executive Licensing Panel

The inspection team recommends the renewal of the centre's licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The centre double checks the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process (Standard Licence Condition (SLC) T71).

Witnessing steps observed during the inspection included egg collection, sperm preparation, embryo transfer and disposal of material and were performed in accordance with CoP requirements. Records of all required witnessing steps were present in 10 sets of notes audited on inspection, with two exceptions detailed below (CoP Guidance 18.4).

What the centre could do better.

In one of the 10 sets of patients' notes audited, the signatures were not recorded of the member(s) of staff witnessing where in the dewar the embryos were placed after cryopreservation and at the disposal of gametes/embryos (SLC T71, CoP Guidance 18.4h and 18.4j). See recommendation 3.

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)
- Counselling (Guidance Note 3)

What the centre does well.

Justification for the use of gametes and embryos in treatment, based on the patient's medical history and therapeutic indications, was documented in the 10 sets of patient notes reviewed on inspection (SLC T49).

An audit of 10 sets of patient notes demonstrated that patients are screened for HIV, hepatitis B and hepatitis C as required by SLC T50. Screening results of satellite patients

are reviewed prior to treatment at the centre. Additional patient testing, including for HTLV-1, is carried out when required (SLC T50c).

The centre uses a CPA accredited laboratory for screening. However, the CPA accreditation status of laboratories used by the centre's satellite partners were not initially known by centre staff. Evidence was provided on the second day of the inspection that all the laboratories are CPA accredited. Centre staff described their plans for monitoring the CPA accreditation status of all relevant laboratories in the future (SLC T21).

The centre performs diagnostic semen analysis but the laboratory is not CPA accredited. However, the centre has a quality management system (QMS), validated procedures and equipment for semen analysis and Health and Care Professions Council (HCPC) registered staff suitably qualified to perform semen analysis and interpret results. The service also participates successfully in the national external quality assessment scheme (NEQAS) for semen analysis. In consideration of these facts, the centre is considered to have a status equivalent to that of CPA (SLC T21).

What the centre could do better.

See page 13 of the report for the accreditation status of the genetic testing laboratory used for the diagnostic analysis of biopsied material (SLC T21).

Donor recruitment, assessment and screening (Guidance Note 11)
Donor assisted conception (Guidance Note 20)

What the centre does well.

The centre has a small egg share programme and also accepts known egg donors introduced by recipients. It also offers surrogacy treatment. The centre doesn't actively recruit sperm donors.

Donor assessment and screening is performed only at OFU and not by its satellite centres.

The centre's donor procedures are supported by SOPs and checklists (SLC T33b). Audit of four sets of donor medical records during the inspection provided evidence that:

- Donors are selected on the basis of their age, health and medical history provided in a questionnaire and in a personal interview with a qualified and trained medical professional (SLC T52a);
- Donors are selected in accordance with the screening requirements of SLC T52 and relevant professional bodies[1], with two exceptions detailed below;
- The laboratory tests required by SLC T52 are carried out by a laboratory which is CPA accredited (SLC T53a).

The centre has procedures in place to identify when additional screening tests may be required (SLC T52g/h).

Donor sperm is quarantined for six months prior to use (SLC T53c) and gamete providers in surrogacy arrangements are screened as donors.

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

Nursing staff reported that where the provider of gametes donated prior to April 2005 has not consented to being identifiable, their gametes and any embryos created using them will only be used in treatment to achieve a sibling pregnancy (SLC T54).

The centre is able to provide donors with information regarding the number, sex and year of birth of persons born as a result of their donation.

Patients receiving treatment with donated gametes are provided with written information on the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not their parent (SLC T63).

What the centre could do better.

Donors are not tested by the centre for their blood group and rhesus status, as recommended by current professional guidance produced by the relevant professional bodies (CoP Guidance 11.21). See recommendation 4.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

The quality management system: Guidance Note 23
The centre has a comprehensive QMS, appropriate for the services provided and is well embedded into the centre's day to day activities (SLC T32).

The centre is ISO 9001:2008 certified and an audit of the QMS was last conducted by its certifying body in November 2012. A copy of the audit report documented no non-conformities and a small number of observations for which corrective actions have been taken.

QIs have been established for all licensed activities (SLC T35).

The centre performs regular audits and a selection of audit reports was reviewed. These included audits of consent, witnessing, donor screening and process audits. The audit scope and methodology is planned carefully and a number of audits reported non-conformities or observations, for which corrective action was documented and implemented. The inspector considered that this demonstrated that audits are used as an effective tool by which to improve the quality and effectiveness of the services provided (SLC T32 and T36).

Regular QMS reviews are held and benchmarking is regularly performed with another centre within the ARP to facilitate continuous and systematic improvement (CoP Guidance 23.12 and SLC T32).

Process validation: Guidance Note 15
The centre's critical processes have been validated in compliance with SLC T72. The laboratory staff have written an embryology techniques book, due to be published, that includes a retrospective analysis of the centre's own data and reference to published studies for all critical processes.

Traceability: Guidance Note 19
The centre has a documented procedure to ensure that the traceability of all consumables, reagents and equipment that come into contact with gametes and embryos is assured, with some exceptions detailed below (SLC T99b).

Containers used in the course of procurement and processing of gametes and embryos are labelled with the patient's full name and unique identifier, with one exception detailed below (SLC T101).

Third party agreements: Guidance Note 24
The centre has written agreements with third parties providing goods and services influencing the quality and safety of gametes and embryos (SLC T111). The centre conducts an annual review to evaluate the ability of third parties to meet the required standards (SLC T112). Five TPAs were reviewed on inspection and were compliant with SLC T114, with one exception detailed below.

Satellite centre management: Guidance Note 24
OFU has agreements with five satellite centres, which accounts for approximately 50% of all patients treated at the centre. Two written agreements with satellite centres were reviewed and covered the requirements of General Direction 0010. A review of several audits demonstrated that the centre regularly evaluates the compliance and performance of all of its satellite centres. Evaluation is performed against relevant SLC requirements by several methods including; on-site reviews, patient record audits and satellite patient satisfaction surveys. Corrective action is taken where improvements are required (SLC T36).

Satellite patient treatment pathways are closely managed by the centre to ensure that the correct procedures are followed. A review of five sets of satellite patient records and discussions with staff, demonstrated that all procedures performed by the satellite centres, including welfare of the child (WoC) assessment, obtaining consent and screening are compliant with CoP requirements, with one exception noted on page 21 of this report.

Premises and facilities: Guidance Note 25
Processing of gametes and embryos takes place in an environment that meets the air quality requirements of SLC T20. Air quality, via particle counts, settle plates and contact plates, is monitored regularly and was last performed in March 2013.

Records of regular cleaning of equipment are kept and audits of cleaning of the centre premises are performed (SLC T26 and T36).

Equipment and materials: Guidance Note 26
All equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms. Defined temperature limits have been set and the centre's monitoring system for incubators, dewars and refrigerators will alarm if the measurements are outside these limits. The centre has an on-call rota for responding to alarms out of

hours. Weekly monitoring of other critical equipment is also performed (SLC T24).

Critical equipment has been validated and is serviced regularly. Revalidation is performed after cleaning or repair (SLC T24 and T25).

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions (SLC T27).

The specifications for critical reagents and consumables used have been approved and documented. Critical reagents and consumables are CE marked, where possible (SLC T30 and T31).

Equipment with a critical measuring function is calibrated against a traceable standard and calibration certificates are retained by the centre (SLC T24).

Adverse incidents: Guidance Note 27
The centre has reported adverse incidents to the HFEA since the last inspection. Evidence of appropriate incident investigation and implementation of identified corrective actions was reviewed on inspection.

The centre has an adverse incident SOP and maintains a 'non-conformities' register. This was reviewed and demonstrated that reportable incidents had all been reported to the HFEA in a timely fashion (SLC T118).

What the centre could do better.

Quality management system: Guidance Note 23
The centre has established QIs for all activities, but the frequency of audit and/or the threshold under which corrective action would be taken is not documented in all cases. Guidance on documenting QIs was forwarded to centre staff after the inspection (SLC T35). See recommendation 5.

Traceability: Guidance Note 19
At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (SLC T101). See recommendation 6.

An audit of five batches of consumables in use in the laboratory was carried out on inspection. The batch numbers of two items did not match that recorded as being in use on the centre's traceability database (SLC T99b). See recommendation 1.

Third party agreements: Guidance Note 24
The TPA with the genetic testing laboratory used for the diagnostic analysis of biopsied material does not include a description of how any results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample (SLC T114f). See recommendation 7.

Satellite centre management: Guidance Note 24
The centre's written agreement with one satellite provider has not been submitted to the HFEA (General Direction 0010). See recommendation 8.

Multiple Births (Guidance Note 7)

Between 01/04/2010 and 31/03/2011, 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 likely to meet the 20% live birth rate target. The inspection team congratulates the centre on this achievement.

Between 01/04/2011 and 30/09/2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This also represents performance that is not likely to be statistically different from the 15% live birth rate target (SLC T123).

What the centre does well

The PR provided evidence to demonstrate compliance with General Direction 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff regularly audit their multiple birth minimisation strategy as part of the QMS audit programme and changes are made as appropriate;
- the centre maintains a log of women receiving multiple embryo transfers who meet the criteria for eSET, including the reasons for variation from the eSET policy and the pregnancy outcome. Evidence was seen in the patient records that discussions are held with patients regarding the risks associated with multiple pregnancy and that a clear explanation of the reasons for transferring more than one embryo is documented (General Direction 0003, 7);
- the centre maintains a log of cases in which three embryos have been transferred (General Direction 0003, 1b). It recorded that three patients have had three embryos transferred to date in 2013, all being over 40 years old (CoP Guidance 7.5b).

What the centre could better

Nothing noted on inspection.

Staff engaged in licensed activity

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

What the centre does well.

The centre has suitably qualified staff to carry out all of the licensed activities and associated services. All staff, where appropriate, are registered with the relevant professional and/or statutory bodies, with one exception (refer to page 15 of this report). The consultant embryologist is a HCPC registered clinical scientist and the nominated registered medical practitioner is registered with the General Medical Council (GMC) (SLC T14 and CoP Guidance 2.19).

Person responsible: Guidance Note 1
Mr Tim Child has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activities to be authorised by the licence (HF&E Act 1990 (as amended) Section 16(2)(c)(i) and (ii)). He has also successfully completed the HFEA PR Entry Programme (T/1157/8).
Staff: Guidance Note 2

An organisational chart is in place which defines accountability and reporting relationships (SLC T11).

Staff at the centre are assessed for suitability by interview, uptake of references and Disclosure and Barring Service (DBS) checks, as documented in the centre's recruitment policy (HF&E Act 1990 (as amended), Section 17(1)(a)).

There is a formal induction training programme for staff, comprising of general orientation and support, mandatory training and an overview of the centre and its departments. Documented evidence of this was seen for an embryologist and nurse (SLC T15).

Evidence was provided that staff are competent in their designated tasks. Regular reviews of staff practice are performed, including for egg collection, ICSI and embryo transfer (SLC T12). Staff are given the opportunity to participate in continuing professional development, including attendance at conferences and external courses. Staff appraisals are performed annually (SLC T15 and CoP Guidance 2.3).

Each department has detailed workforce assessments which are reviewed regularly. All staff interviewed, including the PR, confirmed that the centre is currently operating with a full staff complement. Staffing levels observed in the course of the inspection appeared to be suitable for the present activity and workload. This is a large centre and the atmosphere in the clinic appeared calm and organised at all times (SLC T12).

What the centre could do better.

Nothing noted at the time of this inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Prior to any patient being provided with treatment services the welfare is considered of any child who may be born as a result of the treatment and of any other child who may be affected by that birth.

There is a SOP in place for the process to be followed when carrying out a WoC assessment. Ten sets of patient notes, including those of satellite patients, reviewed on inspection demonstrated that WoC assessments had been completed appropriately prior to treatment (SLC T56).

Discussions with nursing staff confirmed they understood the importance of conducting WoC assessments and that in the event of any concern, patients would be asked to attend an appointment with the Medical Director (SLC T56).

What the centre could do better.

Nothing noted at the time of this inspection.

Embryo Testing

- Preimplantation genetic screening (Guidance Note 9)

- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.

The centre is licensed for embryo testing and offers PGD and PGS. The centre's embryo biopsy procedures are documented in SOPs (SLC T33b). The centre has staff competent to carry out embryo biopsy and competence is regularly re-assessed (SLC T12).

QIs have been established for embryo testing and audits of biopsy procedures against QIs and approved protocols are performed regularly. The report of an audit performed in March 2013 was reviewed and no issues were identified or corrective action required (SLC T35 and T36).

The biopsy procedures have been validated in compliance with SLC T72. The validation approach included substantial literature reviews and consultation with the external testing laboratory.

Procedures are in place to ensure that no sex selection for social reasons is conducted at the centre (SLC T88b).

What the centre could do better.

Genetic testing is conducted by a laboratory that is not currently accredited by CPA or another body accrediting to an equivalent standard as required by SLC T21. The laboratory is working towards accreditation and is due to be inspected by CPA in August 2013. The laboratory used is situated within the centre's premises and the PR considers that due to the quality of the work, discussions with other centres and his first hand knowledge that the laboratory is actively working towards accreditation, this mitigates the risks of non-compliance with SLC T21. See recommendation 2.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12)
- Surrogacy (Guidance Note 14)

What the centre does well.

Evidence was provided on inspection that patients have treatment on suitable licensed premises.

From discussion with staff and patients and observations made on inspection, the inspection team was assured that all licensed activities are conducted in a non-discriminatory manner with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current donors and patients (CoP Guidance 29.3).

Counselling: Guidance Note 3
Counselling is offered to all patients providing consent, as evidenced during discussions with staff, review of the centre's patient information leaflets and via the patient records audit (SLC T60). Counselling is mandatory for those providing consent to donation.

The centre can refer patients for specialist counselling, if required.

Complaints: Guidance Note 28
Patients are provided with information on how to make a complaint (CoP Guidance 4.2k). The centre's complaints log was reviewed on inspection and centre staff described how learning from complaints has led to changes to procedures to improve their services.

Patient feedback
Patient satisfaction is monitored closely by the centre via patient questionnaires. A recent survey conducted between November 2012 and March 2013 received 400 responses, nearly all of which contained positive feedback. Centre staff described the corrective action taken in response to a small number of patient comments.

Thirteen patients provided feedback to the HFEA via completed questionnaires since the last inspection, the majority of whom provided positive comments.

What the centre could do better.

Counselling: Guidance Note 3
The counsellor is not accredited by, nor working towards, accreditation by BICA. The counsellor has worked at the centre for over 20 years, holds a recognised counselling qualification, is a member of the British Psychology Society and participates in continuing professional development. However sufficient evidence to demonstrate that the counsellor meets full equivalence to BICA accreditation was not available, including attendance at BICA's introductory training course and/or similar infertility counselling training (CoP Guidance 2.12 and 2.13) See recommendation 9.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytoplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Four patients were interviewed on inspection and all gave positive feedback about their experience at the centre. They considered that they were given sufficient time to discuss their proposed treatment plan prior to giving consent, had sufficient opportunity to ask questions and that staff were approachable and knowledgeable.

The centre has documented procedures for the provision of information prior to obtaining consent for treatment (SLC T33b).

The centre submitted a suite of patient information prior to the inspection, covering the majority of the requirements of the CoP. Where specific information is not provided in these leaflets, it is either documented on the appropriate local consent form, or provided verbally, for example as part of the patient information evening presentation. Some exceptions are detailed below.

The satellite centres' websites were reviewed prior to inspection. The inspection team considers that appropriate and accurate information is given (Chief Executive's letter (10)(05)). The centre's own website was also reviewed prior to inspection and was compliant with the requirements of Chair's Letter CH(11)02 and the CoP.

Costed treatment plans
Patients are provided with information regarding the cost of their treatment before it commences. A costed treatment plan is generated prior to each treatment cycle and a copy of this is given to the patients (CoP Guidance 4.3).

What the centre could do better.

A small number of errors or areas of concern were identified during the patient information audit conducted prior to the inspection. The findings were discussed with the quality manager on inspection. The details are not described in full in this report, but were provided to the centre post inspection and include:

1. **PGS:** Before seeking consent to treatment including PGS for aneuploidy, patients are

not given written information that covers CoP Guidance 9.1 d, e and g.

2. **Storage of licensed material:** A number of patient information leaflets are not clear as to the storage periods for gametes and embryos or provide inaccurate information on this subject. For example, the centre's 'Donor Insemination' leaflet states that "donated sperm can only be kept for ten years and then must be discarded" (CoP Guidance 17.12b).

See recommendation 10.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

Written consent is obtained from patients prior to treatment (SLC T57) and the centre has a documented procedure for obtaining consent (SLC T33b).

Photographic identification is used to verify patient identity. Copies of photographic identification were present in the patient notes reviewed on inspection (CoP Guidance 5.10).

Ten sets of patient notes, including those of satellite patients, were reviewed on inspection. Appropriately completed consent forms were in place in all cases.

Legal parenthood: Guidance Note 6
Discussions with staff at the centre confirmed that processes are in place to ensure that a woman is not provided with treatment services using embryos or donated gametes, unless she and any man or woman who is to be treated together with her have been provided with information about parenthood laws (SLC T60).

There is a procedure in place to ensure that when a person who has previously consented to be the second parent of any child born as a result of a treatment has withdrawn that consent, the treatment is not provided without first informing the woman being treated that the consent has been withdrawn. Also, where a woman being treated withdraws her consent to a nominated second parent being the legal parent, or consents to a different person being the legal parent of any child born, the centre has a procedure in place to ensure that the nominated second parent is informed of the change in writing (SLC T64b).

Three sets of records of patients who had undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.

What the centre could do better.

Nothing noted on this inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

Premises and facilities: Guidance Note 25
Discussions with staff and a tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence (SLC T1).

Donor compensation: Guidance Note 13
Following discussions with staff and a review of donor records and other documentation, the inspection team considers that no money or benefit is given or received for the supply of gametes or embryos, except where authorised by the Authority. Donor compensation records indicated that compensation paid to donors is within the prescribed limits of General Direction 0001.

What the centre could do better.

Nothing noted at this inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

The centre has documented procedures for storing gametes and embryos (SLC T33b).

The centre has a well developed bring-forward system with dedicated members of staff responsible for its management to ensure that licensed material is not stored beyond its consented storage period. A review of the centre's records demonstrated that written effective consent is in place for all cryopreserved gametes and embryos with three

exceptions (HF&E Act 1990 (as amended), Schedule 3, 8(1) and (2)). The centre's procedure for withdrawal of storage consent includes the provision of a 12 month 'cooling off' period in cases where one gamete provider withdraws consent to embryo storage. At the time of the inspection the centre had invoked this procedure for three couples with embryos in storage and staff were able to demonstrate their understanding of the procedure.

Storage tank audits are conducted biennially and where necessary corrective actions are documented and implemented (SLC T36).

Prior to storage, the providers of gametes and embryos are screened for HIV, hepatitis B and hepatitis C as per the requirements of SLC T50. No seropositive samples are stored on site and staff reported that such samples would be stored at a specialist clinic.

What the centre could do better.

Nothing noted at this inspection.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15)
- Export of gametes and embryos (Guidance Note 16)
- Receipt of gametes and embryos (Guidance Note 15)
- Import of gametes and embryos (Guidance Note 16)

What the centre does well.

There is a SOP in place describing the procedure for the distribution of gametes and embryos (SLC T33b). Laboratory staff ensure that the procedure is followed accurately and that all required information is provided when distributing material (SLC T110).

Security tags with a unique identifying code are used to secure containers prior to transport (SLC T108).

SOPs define the responsibilities and actions that would be required if a distribution was recalled (CoP Guidance 15C).

Import and export of gametes and embryos: Guidance Note 16
Import and export of licensed material is managed by dedicated members of staff. The centre has imported sperm since the last inspection. The records of one set of imported donor sperm were reviewed and include written confirmation that all requirements of General Direction 0006, Schedule 1, were satisfied with one minor exception detailed below.

What the centre could do better.

Import and export of gametes and embryos: Guidance Note 16
Written confirmation from the supplying centre that the sperm samples to be imported meet the UK requirements on screening did not include assurance that a physical examination for genital warts and herpes had been carried out by a clinician before and after the course of donation (General Direction 0006, Schedule 1 (g) and CoP Guidance 11.21). See recommendation 4.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

Embryos are only used for training staff in activities that have been expressly authorised by the Authority (SLC T93).

The donation of embryos for use in staff training is witnessed by two members of staff. This witness step includes checking to ensure that both gamete providers have consented to this use (SLC T94).

What the centre could do better.

The centre's patient information details the nature of the training for which embryos will be used, but does not include information on:

- that the decision whether to donate will not affect their treatment in any way (SLC T97b); and
- whether any information will be fed back to them (SLC T97d).

The centre's research and training SOP does not document the procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T95).

See recommendation 11.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
  - maintaining up-to-date awareness and understanding of legal obligations
  - responding promptly to requests for information and documents from the HFEA
  - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

All patient records reviewed during the inspection were clear and legible and satisfied the requirements of SLC T46.

Centre documents are version controlled and reviewed on an annual basis. All documents reviewed on inspection were within their review period. Changes made to SOPs are communicated to all relevant staff (SLC T34 and CoP Guidance 31.6).

The centre has documented procedures to ensure that patient records are maintained for at least thirty years (SLC T48).

What the centre could do better.

Nothing noted on this inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

The PR provided all the information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner.

Licensed treatment reporting
The centre has a SOP for the submission of data to the HFEA (SLC T33b) and has established QIs for the submission of data. An audit performed in September 2012 included assessing if treatment forms were submitted within the required timeframes. Corrective action was documented and implemented (SLC T35 and T36).

To confirm that data submitted by the centre for inclusion on the statutory register accurately reflects that found in source records on-site, a sample of 73 assorted form type

data submissions were reviewed against source documentation held on patient and donor files. One significant error and a number of minor errors have been notified to the centre for correction. No critical errors or omissions (i.e. errors that would prevent the authority fulfilling its statutory obligations) or systematic errors were identified.

What the centre could do better.

IUI data for 2011 and 2012 have not been submitted (General Direction 0005). See recommendation 8.

Licensed treatment reporting
To determine whether all licenced treatment activity is reported to the HFEA within required timescales, a sample of treatments undertaken over a 12 month period and recorded within the centre's laboratory records was compared to data submitted by the centre for inclusion on the register. The reporting of one of 132 IVF treatments in the audit sample was outstanding at the time of inspection. All DI treatments had been recorded. This finding may indicate that other treatments outside the sample have also not been reported to the Authority in accordance with General Direction 0005.

A significant proportion of the sample, i.e. 50% of IVF and 83% of DI treatments, were submitted outside the period required by General Direction 0005. See recommendation 12.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)
- Disclosure of information, held on the HFEA Register, for use in research

What the centre does well.

Confidentiality and privacy: Guidance Note 30
Discussions held with staff, a review of centre documentation and a tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

Patient records are kept in secure areas and only authorised persons have access to confidential information. Documented procedures ensure records are secure at all times and that systems are in place for maintaining data security. The centre has procedures for arranging for patients to access their records (SLC T43 and T44).

What the centre could do better.

Consent to disclosure of identifying information to researchers
During the review of patient notes, the consent to disclosure to researchers form for a satellite patient's partner was missing.

To determine whether the register properly reflects the consent given by patients and their partners for the use of their information in the HFEA register for research purposes, a sample of 12 completed patient and partner disclosure consents were reviewed against the disclosure consent decisions supplied by the centre to the register. Discrepancies were found in 10 of the 12 cases between the disclosure consents in patient files and the consent decisions submitted to the register. Additionally a donor's consent to non-contact research was incorrectly recorded in the register (General Direction 0007). See Recommendation 13.

5. Changes / improvements since the previous inspection on 27/03/2012

Area for improvement	Action required	Action taken as evidenced during this inspection
The laboratory carrying out the PGS and 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 18 May 2010 it was documented in the report that "The PR should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by SLC T21. This should be accomplished by 1 October 2010" This was considered by the ELP on 12 August 2010.	The PR should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by SLC T21. The PR to provide a realistic time line for the expected accreditation prior to the report being considered by The ELP on 29 June 2012. He should also consider and inform the Executive of what actions he will take should the laboratory not be CPA accredited by December 2012.	Refer to page 13 of this report. **Further action is required.**
The centre has, in the period 2011/2012, taken an average of 88 days to pay their invoices. This is clearly non compliant with Chair's Letter CH(10) which requires that invoices are paid within 28 days.	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 SLC 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.	The centre has not received any HFEA risk tool alerts regarding invoice payment since April 2012. No further action required.
Consent to disclosure to researchers: An audit of patient files highlighted a discrepancy in	The PR to review the systems and processes regarding the recording of consent to disclosure and to	A review of the systems and processes was performed by the centre and corrective action implemented.

consent in three of the files examined compared to registry data held at the HFEA.	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 PR should submit an action plan that includes timescales for completing this audit.	Following an audit performed in August 2012, further corrective action was identified and implemented. Another audit is currently being conducted. Refer to page 21 of this report. **Further action is required.**

Recommendation from Licence Committee 1 December 2011

Recommendation	Action taken as evidenced during this inspection
The minutes of a Licence Committee meeting in December 2011 to consider a Grade A incident noted: 'The Committee hopes that at the renewal inspection next year, the centre provides clear evidence that the new SOPs are being adhered to and would also hope that other centres are following the same practices'.	In discussion with laboratory staff, observations of practice and review of audits performed, it was demonstrated that the new SOPs are being adhered to. No further action is required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. An audit of five batches of consumables in use in the laboratory was carried out on inspection. The batch numbers of two items did not match that recorded as being in use on the centre's traceability database. SLC T99b.	The PR should undertake an audit of consumables/reagents in use in the laboratory against those recorded as being in use on the computer database, to identify whether the inspection observations represent a systemic failure in the traceability procedures or a rare occurrence. A summary report of the review findings including any corrective actions and the timescale for their implementation should be submitted to the HFEA by 1 August 2013. Within three months of the implementation of corrective actions, the centre should re-audit to assess the suitability	An audit will be undertaken as suggested.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	of the corrective actions identified. This audit report should be submitted to the centre's inspector.		
2. The genetic testing laboratory that is used for the diagnostic analysis of biopsied material is not CPA accredited. SLC T21.	The PR should keep the Executive informed on the laboratories progress towards CPA accreditation, including confirmation that the CPA inspection scheduled for August 2013 has been conducted. If CPA accreditation is not achieved by December 2013, the PR should assess whether this laboratory should continue to be used for diagnostic analysis. A report of this assessment should be provided to the centre's inspector by 1 January 2014.	This is the response from Dr. Wells, Director of Reprogenetics (who currently undertake PGD/S analysis for a large proportion of the UK's IVF Units): 'I can confirm that we have a fully operational Quality Management system in place. All of our paperwork was submitted to the CPA many months ago and we are currently awaiting inspection. For your records our CPA reference number is 4021. We have been informed that our inspection will take place in August of this year. In the meantime, our QM system continues to be overseen and audited by a professional Quality Manager. Additionally, the Reprogenetics UK laboratory participates in all of the External Quality Assessment (EQA) schemes available for laboratories specializing in preimplantation	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

		genetic diagnosis (PGD). This is currently the only means of independently assessing the accuracy of diagnostic protocols employed by PGD laboratories. Reprogenetics UK has always received maximum scores in the EQAs it has participated in.' I will contact the HFEA after the lab's CPA inspection.	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. In one of the 10 sets of notes audited, the signatures of the member(s) of staff witnessing two separate procedures were not recorded. SLC T71, CoP Guidance 18.4h and 18.4j.	The PR should ensure that all witness checks are recorded at the time of the procedure. Accurate completion of witnessing records should continue to be monitored as part of the centre's audit programme. The centre has recently completed a witnessing audit. This audit report, including any corrective actions taken, should be submitted to the centre's inspector by the time the PR responds to this report.	Witness checks are always undertaken. I will ensure that they are always recorded. The audit has been forwarded to you and a re-audit has been planned in view of the non-compliance which has been noted.	The centre's last witnessing audit, performed in April 2013, has been submitted. No issues were identified or corrective action required. The PR's response is acknowledged. No further monitoring is required.
4. **Donor screening** Written confirmation from the supplying centre that an imported sperm sample meets the UK requirements on screening did not include assurance that a physical examination for	The PR should ensure that donors of gametes and embryos are screened in accordance with current professional guidance produced by the relevant professional bodies.	I will ensure that donor screening is undertaken in accordance with current professional guidance.	The PR's response is acknowledged. No further monitoring is required.

genital warts and herpes had been carried out by a clinician before and after the course of donation. Donors are not tested for their blood group and rhesus status, as recommended by current professional guidance produced by the relevant professional bodies. General Direction 0006, Schedule 1g and CoP Guidance 11.21.	Confirmation of this should be provided to the centre's inspector by 1 November 2013.		
5. The centre has established QIs for all activities, but the frequency of audit and/or threshold under which corrective action would be taken is not recorded in all cases. SLC T35.	The PR should ensure that the frequency of audit and the threshold at which corrective action will be taken are documented for all QIs. The centre's revised QI list should be provided to the centre's inspector by 1 August 2013.	This will be documented. The revised QI list will be provided.	The centre's revised QI list has been submitted. The frequency of audit and the threshold at which corrective action will be taken has been documented for all QIs. No further action is required.
6. At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name	While it is acknowledged that only one egg collection takes place at a time, the PR should consider the risks of not labelling the tubes used during	A risk assessment has been undertaken. As only a single oocyte recovery (OR) procedure takes place at one time and as only a single	The PR's response is acknowledged. No further monitoring is required.

and a further identifier or a uniquely identifying donor code. SLC T101.	egg collection. The centre's inspector should be informed of any actions taken to mitigate the risks of misidentification as a result of this practice by 1 August 2013.	embryologist, flow hood, and heating block is used, and all are cleared before the next case, then the current practice is considered safe. However, in view of the observation, the SOP has now been changed so that the embryologist performing the OR will confirm at the end of the procedure that all tubes for that patient have been dealt with- the lab OR sheet will then need to be 'ticked' to confirm this.	
7. The TPA with the genetic testing laboratory used for the diagnostic analysis of biopsied material does not include a description of how any results are relayed to the centre, including sign off and confirmation that the result applies to the correct sample. SLC T114f.	The PR should revise the TPA with the genetic testing laboratory to include the requirements of SLC T114f. The PR should also review any other TPAs with third parties that provide test/diagnostic results to the centre and revise if necessary. By 1 November 2013	This will be undertaken by November 1st 2013.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
8. **Information submission to the HFEA** The centre did not submit an annual return for IUI for 2011 or 2012 to the HFEA.	The PR should submit annual returns for 2011 and 2012 immediately, even if no IUIs were performed in this time period.	The annual IUI returns for 2011 and 2012 have now been submitted. The written satellite agreement	The annual IUI returns have been submitted. In 2011, the centre reported 12 cycles of IUI with no pregnancies. In 2012, the centre reported 7

The centre's written agreement with one satellite provider has not been submitted to the HFEA. General Directions 0005 and 0010, 3.	The PR should submit the written agreement with its newest satellite provider immediately. The PR should review the centre's processes for ensuring submission of all information required by General Directions within the timescales specified.	has been submitted. This review is in progress.	cycles of IUI with no pregnancies. Because the data was not submitted to the HFEA within the timescale specified, it was not included in the statistical analysis of the sector's results. Therefore it is not know if the success rates are consistent with the national average. However, due to the small numbers of IUIs performed, it is considered likely to be consistent with the national average. The agreement with the satellite provider has also been submitted. The PR's response regarding the review of the centre's processes for ensuring timely submission in the future is acknowledged. No further monitoring is required.
9. The counsellor is not working towards accreditation by BICA. Sufficient evidence to demonstrate that the counsellor meets full	The PR should ensure that the counsellor can provide evidence of full equivalence to BICA accreditation. By 1 November 2013.	I note the comments regarding BICA equivalence and have discussed this issue with our Counsellor. Roz Shaw-Smith is registered Chartered Counselling Psychologist and	The lead inspector acknowledges the PR's response. Progress with working towards BICA accreditation will be reviewed at the next inspection.

equivalence to BICA accreditation was not available. CoP Guidance 2.12 and 2.13.		full member of The British Psychological Society conforming to all the requirements of Chartered Status with both a degree and specialist Counselling Post Graduate qualification. She is also registered with the HPC, a government regulatory requirement for all practising psychologists. Hitherto this has been seen as exceeding the BICA standard by the Authority. In this capacity she has acted as a specialist inspector for the HFEA and has 20+ years fertility counseling experience. However, in response to the inspection report she will undertake the described BICA training and development to achieve accreditation.	
10. A small number of errors or areas of concern were identified during the patient information audit conducted prior to the inspection. The findings were discussed with the quality manager on inspection and full details were provided post inspection. The full details	The PR should review and revise the areas of concern noted by the inspection team in the centre's patient information. Confirmation of completion of the revisions to be provided by 1 August 2013. A sample of patient information leaflets will	This will be undertaken as requested.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

will not be included in this report, but include: **PGS:** Before seeking treatment to treatment including PGS for aneuploidy, patients are not given written information that covers CoP Guidance 9.1 d, e and g. **Storage of licensed material:** A number of patient information leaflets are not clear as to the storage periods for gametes and embryos. For example, the centre's 'Donor Insemination' leaflet sates that "donated sperm can only be kept for ten years and then must be discarded' (CoP Guidance 17.12 (b)).	then be requested for submission and review by the centre's inspector.		
11. **Use of embryos for training** The centre's patient information leaflet regarding the use of embryos for the purposes of staff training does not include information on:	The PR should review and revise the patient information leaflet regarding the use of embryos for the purposes of staff training to ensure that all information required by SLC T97 is included.	This will be undertaken as requested and the research and training SOPs updated. We will ensure that at least one of the two embryologists witnessing embryos designated to training or research is not an end user	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

• that the decision whether to donate will not affect their treatment in any way; and • whether any information will be fed back to them. The centre's research and training SOP does not document the procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services. SLC T95 and T97b/d.	The PR should review and revise the centre's research and training SOP to ensure the procedures required by SLC T95 are documented. By 1 August 2013.	which will avoid a conflict of interest.	
12. **Licensed treatment reporting** The reporting of one of 132 IVF treatments in the audit sample was outstanding at the time of inspection. This finding may indicate that other treatments outside the sample have also not have been reported to the Authority in accordance with Direction 0005. A significant proportion,	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for delay and non-reporting to be identified and addressed. A summary report of the review findings including	This will be undertaken as requested.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

50% of IVF and 83% of DI treatments in the audit sample have been submitted to the HFEA outside the period required by General Direction 0005. SLC T9e, SLC T41 and General Direction 0005.	any corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 1 August 2013.		
13. **Consent to disclosure of identifying information to researchers** During the review of patient notes, one consent to disclosure form, from a satellite patient's partner, could not be found. Discrepancies were found in 10 of the 12 patient notes between the completed patient/partner disclosure consents on patient files and the related consent data submitted by the centre for inclusion on the register. Additionally a donor who had agreed to non-contact research was incorrectly recorded.	The centre is currently performing its own consent to disclosure audit. A summary report of the findings, including corrective actions and the timescale for implementation should be submitted to the centre's inspector by 1 August 2013. Three months after the implementation of corrective actions the centre should audit a random sample of 10 sets of patient records to ensure that consent to disclosure to researchers taken from patients has been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit	The current audit will be submitted and the re-audit undertaken as requested.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and General Direction 0007. Although this was also an issue at the last inspection, the centre has been active in reviewing and re-auditing its processes. For this reason, the inspection team does not consider that this needs to be escalated to a 'major' non-compliance.	should be submitted to the centre's inspector for cross reference against the records held by the HFEA. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application by researchers is made for the release of that information.		

Additional information from the Person Responsible
I wish to thank the inspectors for their thorough but fair report.

HFEA Executive Licensing Panel Meeting

19 July 2013

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

Minutes – Item 1

Centre 0035 – (Oxford Fertility Unit) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair) Matthew Watts – Regulatory Policy Manager Joanne Anton – Policy Manager	Rebecca Loveys

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 large centre which has held a licence with the HFEA since 1992.

2. The Panel noted that the centre provides a full range of fertility services and that it was relocated to purpose-built premises in 2009.

3. The Panel noted that the centre is on a four-year licence due to expire September 2013, and that the inspection took place on 30 April and 1 May 2013.

4. The Panel noted that for the 12 months to 31 March 2013, the centre provided 2356 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that in the 12 months to 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%, and that this represents performance that is not likely to be statistically different from the 15% live birth rate target. The Panel commended the centre's low multiple births rate.

6. The Panel noted that, at the time of inspection, two major and 11 other areas of non-compliance were identified by the Inspectorate.

7. The Panel noted that, since the time of inspection, five other areas of non-compliance have been addressed by the PR, and a commitment has been made to address the remaining two major and six other areas of non-compliance.

8. The Panel noted the efforts made at the centre to address areas of non-compliance identified during its interim inspection of 27 March 2012 and urged the PR to address the outstanding areas of non-compliance, in particular that which concerns consent to the disclosure of information for researchers.

9. The Panel noted that the centre did not submit IUI data for 2011 or 2012 and, whilst up to date IUI data has now been submitted, that the submission of IUI data annually to the HFEA is obligatory.

Decision

10. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

11. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

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

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

14. The Panel agreed with the Inspectorate's recommendations made in the report and endorsed the recommendations. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: Date: 26 July 2013

Juliet Tizzard (Chair)