Inspection Report

Date of Inspection: 19 and 20 October 2011
Purpose of inspection: Renewal of Treatment and Storage Licence
Length of inspection: 14 hours
Inspectors Parvez Qureshi
Sara Parlett
Kathryn Mangold
Sheila Pike
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Ricky Gourd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 13 October 2010 and 30 December 2011

Date of Executive Licensing Panel: 13 January 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (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 which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Bourn Hall Clinic
Centre number	0100
Licence number	L0100/13/c
Centre address	Bourn, Cambridge Cambridgeshire CB23 2TN
Person Responsible	Dr Michael Macnamee
Licence Holder	Mr Peter Brinsden
Date licence issued	05/07/2007
Licence expiry date	31/03/2012
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Bourn Hall Clinic was first licensed in 1991. It has a good history of compliance with no previous conditions on its licence. The current licence was granted on 5 July 2007 and will expire on 31 March 2012.

The premises are based within a converted manor house and an adjacent purpose-built facility and since the last inspection in October 2010 the premises have not undergone any major changes. The premises provide a well maintained and suitable environment for patients, centre staff and clinical and laboratory processes. Bourn Hall Clinic provided approximately 3000 treatment cycles between October 2010 and September 2011.

The PR has academic qualifications and more than two years of practical experience, as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). The PR has successfully completed the HFEA PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01 Oct 2010 - 30 Sep 2011*
In Vitro Fertilisation (IVF)	1285
Intracytoplasmic sperm injection (ICSI)	1031
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer	544
Donor insemination	71
Egg share	17
Egg donation (non egg share)	27
Intra uterine insemination (IUI)	80 (Note: cycles provided in the period 1 January to 31 December 2010.

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

Outcomes*

For IVF/ICSI, HFEA held register data for the period July 2010 – June 2011 show the centre's success rates are in line with national averages with the following exceptions:

Frozen ICSI-in patients aged < 40 and 40+ respectively and Frozen IVF-in patients aged< 40 and 40+ respectively. In these treatment groups success rates appeared to be below national average but this is considered likely to be due to a failure to submit early outcome forms: the analysis of success rates performed assumes that where there is no submission of an early

outcome that the cycle's outcome is negative.

For the year 2010 the centre reported 80 cycles of partner IUI with 12 pregnancies. This equates to a 15% pregnancy rate.

*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 they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR is suitable and has, with the exception of the areas of non-compliance identified in this report, 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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including seven major areas of non-compliance and three other areas of non-compliance or areas of poor practice.

Since the inspection visit on 19 and 20 October 2011 the PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance*:*

- The PR should ensure that all critical processes are validated. This validation may be based on studies performed by the establishment itself, data from published studies or from well-established processing procedures, or by retrospective evaluation of the clinical and laboratory results.
- The PR should ensure that laboratories who undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, obtain CPA (UK) Ltd or equivalent accreditation (NB. this includes the following disciplines: andrology; clinical genetics; haematology; bacteriology; virology; clinical biochemistry).
- The PR should ensure that a clear explanation of the reasons for transferring more than one embryo where the patient meets the criteria for elective single embryo transfer (eSET) is documented in the patient's notes.
- The PR should ensure that should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent 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.
- The PR should ensure the accuracy of data provided via the electronic data interface EDI system regarding consent to the disclosure of identifying information to researchers.

Other areas of practice that require improvement:

- PR should ensure that the witnessing SOP is updated to include disposal of fresh embryos.

- PR should ensure that the centre's procedure for withdrawing storage consent regarding the provision of a 12 month 'cooling off' period states that the 12 month period must not extend beyond the statutory storage period.
- PR should ensure that a counselling SOP is finalised.

The PR's response to the inspection report does not appear to give a commitment to implement the following recommendations. The PR should ensure these recommendations are implemented within the prescribed timescales.

Major areas of non compliance

- PR should ensure all licensed treatment cycles are reported within the required timeframe to the HFEA.
- The PR should ensure that the standard operating procedures (SOPs) for the processes by which sperm and egg donors, and providers in sperm sharing arrangements, are recruited, assessed and screened, are finalised.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions.

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.

Witnessing – Guidance Note 18

There is a SOP in place for the process to be followed when carrying out witnessing, (Standard Licence Conditions (SLC) T33b). A review of the witnessing SOP, discussions with staff and witnessing observations carried out in the laboratory demonstrated that processes are in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. This includes the witnessing of patient identity and oocytes delivered for transport IVF. The scientific inspector noted that the witnessing checks are carried out and documented appropriately at the time the procedure takes place (SLC T71).

All key witnessing steps are recorded in laboratory notes (SLC T71). Six sets of patients' notes were audited and it was noted that all witness steps had been performed as appropriate.

Evidence was provided to the inspection team showing that the centre has established quality indicators (QI) relevant to witnessing; reports of audits performed were observed for June/July 2011. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing (SLC T15 (a)).

What the centre could do better.

Witnessing – Guidance Note 18

Witnessing of disposal of fresh embryos is performed but it is not explicitly stated in the SOP (SLC T33b). The laboratory manager was aware of this and explained that it would be included in the new overarching witnessing SOP that is currently being drafted.

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.

Audit of patient files during the inspection found justification for treatment, medical history and laboratory test results. Evidence was provided by the PR showing blood tests are carried out in an accredited laboratory.

Counselling: Guidance Note 3
Counselling is offered to all patients and donors providing consent, as evidenced during the review of the centre's patient information leaflets (Act schedule 3, S.3 (1)(a). An audit of patient records demonstrated that the offer and uptake of counselling is documented. The centre has established QIs for counselling; reports of audits performed were observed for July 2011. No corrective action was required (SLCs T35 and T36).

Documented evidence of the assessment of their competence to provide counselling was seen for all three counsellors working at the centre (SLC T15 (a)). One counsellor is accredited under the British Infertility Counselling Association (BICA) accreditation scheme and the other two are working towards BICA accreditation. In addition all three have completed the centre's training and induction programme (SLC T15)

The centre can refer patients for specialist counselling, if required. One of the three counsellors has a nursing background in oncology and where appropriate, cases are referred to her. All other specialist referrals are made by the clinical lead.

What the centre could do better.

Counselling: Guidance Note 3
Only a draft counselling SOP was made available for the inspection (SLC T33b).

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

Donor recruitment, assessment and screening - (Guidance Note 11)
The centre has a small sperm donor programme. At the time of the inspection the PR reported that there were three active sperm donors.

The centre also has an active recruitment programme in place for sperm and egg sharing. The clinical lead confirmed that, in egg sharing arrangements, treatment services are

provided to the egg share donor in the course of the donation cycle, unless there is a medical reason why they cannot be provided at that time (Directions 0001)

All screening undertaken was observed to be in accordance with current professional guidelines and carried in house or by an external laboratory which is CPA accredited (SLC T53a). As reported in the interim inspection of 13 October 2010, HIV and Hepatitis B and C screening tests are carried out in a laboratory which was inspected in May 2010 and re-licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA). The inspection was performed against MHRA Good Clinical Practice (GCP) guidelines, which were reviewed during the last inspection and were considered to be comparable with CPA UK Ltd requirements for accreditation.

Six sets of notes were audited and all were found to contain relevant screening results (SLC T52). The PR also reported that procedures were in place to identify when additional screening tests may be required (SLC T52(h). The clinical lead confirmed that sperm is quarantined for 180 days followed by repeat screening of the donor (SLC T53(c)).

The centre has established QIs relevant to donor recruitment, assessment and screening, reports of audits performed were observed for February 2011. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff were able to demonstrate their competence in this process (SLC T15(a)).

Payments for Donors (Guidance Note 13)
The PR reported that where applicable donors are reimbursed the actual expenses and loss of earnings as prescribed by Directions and a record of this is kept (Directions 0001). The PR also reported that currently the centre does not import gametes for use in donor treatment but confirmed that Directions 0001 would be complied with regarding compensation for loss of earnings.

Donor assisted conception -(Guidance Note 20)
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 (a)).

The PR reported that the centre has only used donor gametes or embryos created using donor gametes from identifiable donors. Treatments with non-identifiable donors are limited to those for sibling use (SLC T54).

What the centre could do better.

The centre has donor recruitment, assessment and screening SOPs in place which document the clinical processes to be followed but these have not been finalised (SLC T33b).

Good clinical practice

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

What the centre does well.

The quality management system – Guidance Note 23
The centre has a quality management system (QMS), which incorporates the HFEA licensed activities undertaken by the centre (SLC T32).

The QMS consists of a quality manual and training and reference manuals, as required by SLC T33. The centre has established objectives and QIs for licensed activities and has conducted ongoing audits. Evidence of audits for consent, welfare of the child (WoC), provision of information and witnessing were seen. The findings of the audits and, where required, the corrective actions taken were also seen on inspection (SLC T36).

The centre has processes in place for the annual review of the performance of the QMS to ensure continuous and systematic improvement. Evidence of this was submitted as part of the renewal application.

There is a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed during the course of the inspection.

Traceability - (Guidance Note 19)
The centre has a process in place to ensure all gametes and embryos are traceable from procurement to patient treatment or disposal (SLC T99). All relevant data relating to anything coming into contact with those gametes or embryos is traceable. Four batches of different reagents in use in the laboratory were cross referenced to the centre's database recording traceability data and no discrepancies were noted.

Containers are, at all stages of procurement, processing and storage, labelled with the patient's full name and medical number (SLC T101). Staff reported that the centre has a procedure in place to ensure data necessary for traceability is stored for at least 30 years (SLC T103).

The centre has established QIs relevant to traceability; reports of audits performed were observed for March 2011. No issues were identified (SLCs T35 and T36). Laboratory staff were able to provide documented evidence of training in traceability procedures (SLC T15 (a)).

Process Validation - (Guidance Note 15)
Laboratory staff provided evidence of comprehensive validation of a number of critical procurement and processing procedures which influence the quality and safety of gametes

and embryos. Validation records were based on Association of Clinical Embryologist ((ACE) guidelines and include reference to published studies, QI evaluation and patient treatment reviews (SLC T72).

Equipment and materials - (Guidance Note 26)
Laboratory staff provided documented evidence of the regular cleaning and disinfection of equipment, maintenance and regular inspection of equipment in accordance with manufacturer's instructions. Records of annual servicing of a centrifuge, microscopes and flow hoods demonstrated this (SLCs T23 and T26).

Critical equipment has been validated using the ACE templates. Comprehensive evidence of equipment validation, including temperature mapping, was reviewed for two incubators, a dewar and a fridge. The laboratory manager explained that periodic reviews of the validation status of critical equipment are performed biennially (SLC T24).

The laboratory manager confirmed that revalidation of equipment would take place after repair, but that this had not yet been necessary. However, evidence was provided that following the relocation of a flow hood from centre 0188, re-validation was performed prior to use (SLC T25).

Documented procedures are in place for the operation of all critical equipment, evidence of this was seen for a number of key pieces of equipment including a centrifuge and a freeze machine. The centre has procedures in place for the action to be taken if equipment malfunctions or fails (SLC T27).

All equipment that affects critical processing or storage parameters is subject to monitoring alerts and alarms. Dewars are continuously monitored for both temperature and liquid nitrogen level. Incubators, refrigerators and low oxygen alarms are also continuously monitored. Defined limits for critical parameters have been set and alarms are relayed to centre staff out of hours. Daily checks, including the temperature of heated stages and tube heaters were seen to be performed. Where measurements fall outside of specified ranges, evidence was provided that equipment is removed from use. Evidence was seen that where testing of equipment demonstrated that specified ranges were not achieved. Equipment with critical measuring functions are calibrated against traceable standards and evidence of this was seen for both a thermocouple and a particle counter (SLC T24).

Instruments or devices used for the procurement of gametes and embryos are validated or specifically certified and regularly maintained. Laboratory staff reported that where possible the centre uses CE marked consumables and this was seen for a selection of items seen on inspection (SLCs T28 and T30).

Premises – suitability of the premises and air quality (Guidance Note 25)
The activities authorised by the licence are carried out in the premises specified in the licence with the exception of those activities which are undertaken by transport/satellite centres or by a third party (SLC T1). All licensed premises are located within the same building.

The centre has a detailed SOP describing the process for monitoring air quality, including action to be taken if the required air quality is not achieved (SLC T33(b)).
Particle counts and microbial monitoring are performed three monthly by an external

company. Detailed records reviewed demonstrated that the air quality of both the background and critical working environment meets the requirements of SLC T20.

Adverse incidents - (Guidance Notes 27)
A documented procedure for the reporting of adverse incidents to the HFEA was seen during the inspection SLC T118. The centre has reported all the required incidents to the HFEA since the last inspection in October 2010. Staff were aware of reporting incidents within the required timeframe.

Third party agreements (Guidance Note 24)
A list of all third party agreements established with third parties who provide goods and services that influence the quality and safety of gametes and embryos was seen by the inspection team (SLCs T111 and T115). The director of quality reported that no issues have arisen with regard to the ability of third parties to meet the required standards. She also reported that site visits are made to key critical suppliers. The centre also has a process in place to pre-evaluate a potential supplier prior to establishing a third party agreement (SLC T112). A review of three third party agreements showed that their content was compliant with requirements. (SLC T114).

What the centre could do better.

Process Validation - (Guidance Note 15)
The processes for oocyte vitrification, assisted hatching, use of pentoxyfilline and use of enzymes post testicular biopsy have not been validated (SLC T72).

Premises – suitability of the premises and air quality (Guidance Note 25)
The laboratory manager explained that semen analysis for initial diagnosis is performed at the centre. The laboratory is not currently accredited by CPA (UK) Ltd or another body accrediting to a similar standard, but they are in the process of working towards ISO 17025 accreditation (SLC T21).

▶ Multiple Births (Guidance Note 7)

For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%[1]

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than the target.

What the centre does well

Ongoing monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123)

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

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

- 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 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 the centre could better

Out of three sets of notes reviewed only one was found to contain a clear explanation of the reasons for transferring more than one embryo (Directions 0003).

Staff engaged in licensed activity

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

What the centre does well.

Person Responsible (Guidance Note 1)
With the exception of the areas of non-compliance identified in this report, the PR has carried out his duties in accordance with Section 17 (1) (a) of the HF&E Act 1990 (as amended) as documented throughout the body of this report.

Staff (Guidance Note 2)
An organisation chart is in place which defines accountability and reporting relationships (SLC T11). The centre has access to a registered medical practitioner who is able to advise on and oversee the medical activities (SLC T16).

The centre has assessed the workforce requirements within the last year (SLC T12). The PR reported that currently they are operating with a full staff complement and he considered that the number of staff is adequate for the current volume of work being undertaken by the centre (SLC T12).

There is a documented induction programme in place for all staff; evidence of this was seen in the training records for a member of the nursing staff, a trainee embryologist and counsellors. Staff records included job description, mandatory training undertaken and documented evidence of having demonstrated competence in their designated tasks including United Kingdom National External Quality Assessment Service (UK NEQAS) for sperm assessment (SLCs T12 and T15).

A review of staff training records showed that staff participate in continuous professional development (CPD), training courses, embryo grading and conferences (European Society of Human Reproduction and Embryology (ESHRE) and ACE) and in house training and development (SLC T15).

Medical, nursing, scientific and counselling staff are appropriately registered or in the

process of registering with their respective professional bodies (SLC T14).

What the centre could do better.

Nothing noted.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child
There is a SOP in place for the process to be followed when carrying out a WoC assessment (SLC T33(b)). The PR and the Nurse Co-ordinator reported that prior to any patient being provided with treatment services the welfare 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 is considered. Evidence of this was seen from a review of patients' notes which contained WoC forms completed and signed by both partners then reviewed by a clinician (SLC T56).

The centre has established QIs relevant to the assessment of WoC and these were audited in September 2010. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff who conduct WoC assessments were able to demonstrate their competence in this process as evidenced in their training and induction programs (SLC T15(a)).

As the centre provides treatment involving surrogacy, WoC assessments are carried out for both the commissioning couple and the surrogate and surrogate's partner where relevant (SLC T56).

What the centre could do better.

Nothing noted.

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) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly - (Guidance Note 29)
All licensed activities are conducted in a non-discriminatory manner. Although the centre is located in a listed building, arrangements are in place for disabled access with ramps to the ground floor entrance. Most of the patient treatment occurs on the ground floor.

Confidentiality and privacy - (Guidance Note 30)
Discussions held with staff, a review of information submitted for the inspection and a tour of the premises indicated that information about patients is not disclosed unless under circumstances permitted by law (SLC T43).

Confidentiality procedures are embedded in a number of centre SOPs and also forms part of the staff induction programme and employment contract (SLCs T43 and T33(b)). Confidentiality was audited in December 2010 and where required corrective actions were documented and implemented (SLCs T35 and T36).

There is a SOP in place for the control of access to health data and records. The SOP covers maintaining data security measures and safeguarding against any changes being made to patient/donor records (SLC T44(a)).

Complaints (Guidance Note 28)
There is a complaints procedure in place and staff were able to demonstrate their understanding of how they would resolve a complaint in a timely manner. Since the last inspection in October 2010, no complaints have been made to the HFEA.

Provision of costed treatment plans (Guidance Note 4)
Prior to commencement of treatment, all patients are provided with a personalised costed treatment plan. The plan provides cost details for the main elements of the proposed

treatment. Patients are also informed of any possible changes to the plan, such as medications, which may be incurred depending on their course of treatment. Staff reported that patients are given the opportunity to discuss the costed treatment plan with the clinical staff prior to treatment (CoP guidance 4.3).

Surrogacy (Guidance Note 14)
The gamete providers in surrogacy arrangements are both screened and registered as donors. All surrogacy cases are presented to an ethics committee. Both the commissioning and surrogate couples are seen separately by a consultant and a counsellor before cases are presented to ethics committee.

What the centre could do better.

Nothing noted

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) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information (Guidance Note 4)
Staff reported that all relevant patient information is discussed with patients during the consultation stage and a record of this is kept in the notes. Evidence of this was seen during a review of patients' notes showing that a checklist for providing information is in place and being used. There is a SOP for the process to be followed when providing information to patients prior to consenting to treatment (SLC T33(b)).

Information provided at the time of inspection, including an audit of patient records; an audit of patient information material submitted for the inspection; discussion with staff; patients and the review of the responses from the HFEA patient questionnaire showed that relevant information is provided to patients before treatment is provided.

The centre has established QIs relevant to the provision of information and these were audited in June and September 2010. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff were able to provide documented evidence of their competence to provide information for those consenting to treatment (SLC T15(a)).

What the centre could do better.

Nothing noted.

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.

Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
Written consent is obtained before gametes or embryos are used in treatment or stored, this was noted during review of the patients' notes and the laboratory worksheets. This was also confirmed by the patients interviewed during the inspection. There is a SOP in place for the process to be followed when obtaining consent. A checklist is also kept in the notes to capture that consent forms are discussed with patients during medical consultations (SLC T33(b)). Staff confirmed that the identity of the person providing consent is verified, photographic evidence is included in patient records and in the database maintained by the centre (CoP 5.10). Staff reported that the identity of the person who gave consent is also cross referenced to the records and the database before treatment is provided (CoP 5.11). Nursing staff confirmed that satellite providers who obtain consent use the same procedures as the centre.

Evidence was provided by staff showing that the centre has established QIs relevant to obtaining consent and these are audited and where required corrective actions are documented and implemented (SLCs T35 and T36). A report of the consent audit conducted in March 2011 was made available on inspection.

The centre has a SOP in place to ensure that all stored gametes and embryos are within their statutory and consented storage periods. The centre operates a comprehensive bring forward system to ensure that patients are provided with sufficient notice regarding the end of the statutory storage period (CoP 17.8). 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. Staff interviewed were able to demonstrate their understanding of the 'cooling off' period.

Staff provided documented evidence of the assessment of their competence to take consent. Evidence of this was seen during review of staff records (SLC T15a).

Consent to legal parenthood - (Guidance Note 6)
The centre has a SOP in place to obtain the relevant written records of consent to parenthood before treating a woman with donor sperm or embryos. Relevant written consents were seen in five patient records audited. Also, checklists were seen to be completed showing that the relevant parenthood laws have been discussed (SLC T60).

The centre has a procedure in place to ensure that no treatment is provided where a person who has previously consented to be the second parent of a child born has withdrawn their consent to parenthood before informing the woman being treated that they have withdrawn it. Also, in the event of a nominated second parent withdrawing their consent to parenthood then a procedure is in place to ensure that the named woman is not treated until she is informed of this (SLC T64b).

What the centre could do better.

Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
The centre's procedure for withdrawing storage consent regarding the provision of a 12 month 'cooling off' period does not state that the 12 month period must not extend beyond the statutory storage period.

Consent to legal parenthood (Guidance Note 6)
Should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born, the centre does not have a procedure in place to ensure that the nominated second parent is informed of the change in writing SLC T65.

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.

Legal requirements
All licensed activities take place only on licensed premises other than those conducted at the satellites centres. The inspection team considered that all staff interviewed displayed in their responses appropriate respect for the special status of the embryo when carrying out licensed activities. Also all gametes and embryos are procured and used in a lawful manner, with appropriate consent.

What the centre could do better.

Nothing noted.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

Storage of gametes and embryos (Guidance Note 17)
The centre has a SOP in place documenting the process to be followed when storing gametes and embryos (SLC T33(b)).

Evidence was provided by laboratory staff that the centre has established QIs relevant to storage. Dewar audits are performed on a rolling basis and these were observed for 2010/2011 and where required corrective actions were documented and implemented

(SLCs T35 and T36).

Documented evidence was observed in the file of the newest member of the laboratory staff of the assessment of their competence in storing cryopreserved material (SLC T15a).

Prior to storage, providers of gametes and embryos are screened for HIV, Hepatitis B and Hepatitis C. Laboratory worksheets include check points to ensure that the screening status is reviewed prior to storage. The laboratory manager confirmed that the centre does not store samples from patients who have positive screening test results.

What the centre could do better

Nothing noted.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

Distribution and receipt of gametes and embryos

The centre has a SOP describing the procedure for the distribution of gametes and embryos, including the required labelling of the shipping container (SLC T33 (b) and T107). The centre uses receipt and dispatch checklists to ensure the procedure is followed accurately and that all required information is provided, as evidenced during the review of a completed checklist for the receipt of imported sperm (SLC T110). The dispatch checklist includes the requirement to:

- Log the temperature of the shipper at the start of transport (SLC T107);
- Record the date and start time of transport (SLC T107);
- Seal the container with a security tag prior to transport (SLC T108);
- Submit gamete/embryo movement forms to the HFEA (General Direction 0005).

Evidence of validation of the temperature of the dry shipper was seen (SLC T108).

The SOP also defines the responsibilities and actions that would be required if a distribution was recalled, including the investigation of the recall as an adverse incident. The centre has a third party agreement in place with a courier that ensures the required conditions are maintained during the distribution of samples (SLC T111).

Import of gametes and embryos (Guidance Note 16)

Between January and April 2011 the centre has imported two sperm samples. The staff confirmed that the samples were received with the appropriate documentation to satisfy the PR that the requirements of HFEA Direction 0006 had been met. A review of the

supporting documentation confirmed that the requirements of General Direction 0006 had been complied with.
What the centre could do better. Nothing noted.

Use of embryos for training staff (Guidance Note 22)
What the centre does well. Centre staff confirmed that embryos are not currently used for the purpose of training staff at the centre.
What the centre could do better. ----

4. Good governance and record keeping

Focus

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

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

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Record keeping and document control: Guidance Note 31
All patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

What the centre could do better.

Nothing noted.

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

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

What the centre does well.

Obligations and reporting requirements of centres – Guidance Note 32
The PR provided all 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

99% of all patient treatments and treatment related forms that were submitted to the HFEA were found to have been submitted within the specified time.

An audit of the completeness of HFEA treatment form submission was carried out to ensure that all treatments within a sample period had been reported to the HFEA. All licensed activity within this time period was found to have been reported.

The quality of data submission was also audited. The audit found this to be acceptable. However, some improvements could be made and these are detailed in the next section.

What the centre could do better.

Although the quality of data input onto forms was considered to be satisfactory, there were some errors. There was also an issue with the 'congenital abnormality' section on outcome forms. However, there is a chance that this could be an IT system error where centre staff input details that do not copy to the final HFEA electronic form.

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 information submitted for the inspection and a tour of the premises indicated that information about patients is not disclosed unless under circumstances permitted by law (SLC T43)

Disclosure of information, held on the HFEA Register, for use in research

The centre seeks consent from relevant parties to the disclosure of information held on the HFEA register to medical or other researchers. During an audit of patient records it was noted that the appropriate HFEA consent to disclosure had been completed in all sets of records and had also been recorded accurately, except for two discrepancies.

What the centre could do better.

Disclosure of information, held on the HFEA Register, for use in research

Discrepancies were found between two partner disclosure consents as regards the use of register information for research.

5. Changes / improvements since the previous inspection on 13 October 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
GN11: Donor recruitment The centre does not have documented procedures describing recruitment, assessment and screening processes to be used for sperm and egg donors or providers in sperm sharing arrangements, non-compliant with SLC T33b.	The processes by which sperm and egg donors, and providers in sperm sharing arrangements, are recruited, assessed and screened, should be documented if those activities are carried out by the centre.	The relevant SOPs are currently under review and are due for completion by the end of the year. Further action required.
GN11: Donor recruitment The centre does not currently monitor QIs for its sperm and egg donor and sharing processes, non-compliant with SLC T35.	QIs for the sperm and egg donor and sharing processes should be identified, documented and monitored.	QIs relevant to donor recruitment have been established. No further action required.
GN11: Donor recruitment The centre has not audited donor recruitment, assessment and screening processes against the SOPs, the regulatory requirements and data from QI monitoring in the last two years, non-compliant with SLC T36.	When SOPs for sperm and egg donor and sperm sharer processes have been documented and QIs for donor and sharer processes have been established (by 13 January 2011; see above), the centre should audit donor and sharer recruitment, assessment and screening processes against the SOPs, the regulatory requirements and data from QI monitoring.	The centre has established QIs relevant to donor recruitment and these were audited in February 2011. No further action required.
GN30 Confidentiality and Privacy Audit of confidentiality and privacy processes against the approved protocols, the regulatory requirements and QIs, has not been performed in the last two years.	The centre should audit processes related to ensuring patient confidentiality and privacy, against the SOPs, regulatory requirements and QIs.	The centre has established QIs relevant to confidentiality and privacy and these were audited in December 2010. No further action required.
GN6: Legal Parenthood Processes to be followed	Processes to be followed when a patient has withdrawn	This process is due for completion by the end of the

when a patient has withdrawn consent to her nominated second parent being treated as the legal parent, or a nominated second parent has withdrawn consent to be considered as a legal parent, have not been documented. Such documented SOPs are required by SLCs T64b and T65.	consent to her nominated second parent being treated as the legal parent, or a nominated second parent has withdrawn consent to be considered as a legal parent, should be documented.	year. Further action required.
GN7: Multiple births When patients fulfil eSET criteria but choose to have a double embryo transfer, the risks of a multiple birth are, according to centre staff, discussed with the patient. The fact that the conversation occurred and the reason for the double embryo transfer are logged in patient records. It is not specifically logged in patient records however that the conversation included verbal information regarding the risks of a multiple birth, as required by Direction 0003, paragraph 7b.	When patients fulfil eSET criteria but choose to have a double embryo transfer, a summary of the contents of the clinician's discussion with the patient should be logged in the patient record, including that the risks of a multiple birth have been discussed again with the patient.	Out of three sets of notes reviewed only one was found to contain a clear explanation of the reasons for transferring more than one embryo where patient met criteria for eSET. Further action required.
GN18: Witnessing Review of process SOPs indicated that one witnessing step required by CoP Guidance 18.4 was not documented, this being the witnessing of the placing of frozen sperm into storage (SOP K3).	SOP K3 should be revised to include that the placing of frozen sperm into storage should be witnessed.	The centre's sperm freeze SOP was reviewed on inspection and included the requirement to witness the placing of frozen sperm into storage. No further action required.
GN18: Witnessing SOP K11 states that the HFEA CoP permits the location in which embryos are placed in a storage dewar to be witnessed and signed off retrospectively.	SOP K11 should be reviewed to ensure that it states that all witnessing steps are performed and documented in a contemporaneous manner.	The centre's SOP was reviewed and no longer includes the option to retrospectively witness storage location. The laboratory manager confirmed that no retrospective

There is no such advice in the 8th edition of the CoP; all witnessing steps must be performed and documented contemporaneously.		witnessing steps are performed. No further action required.
GN13: Donor payment Document IS305R02 states that patients can claim £50 per day at the centre to cover travelling expenses and childcare, as well as up to £250 per course of donation to compensate for loss of earnings, by completion of an expenses claim form. Nowhere in IS305R02 does it say that expenses need to be receipted or justified in any other way, or that the exact amounts of their expenses need to be recorded and claimed for by the donor. Review of donor payment records indicated that exact £50 'day rate' and £250 'loss of earnings' payments have been made without any record of receipts being shown or retained by the centre. These methods of donor reimbursement and the SOP which describes them are non-compliant with Direction 0001. Document IS305R02 also refers to 'anonymous donors'. Donors can no longer be considered anonymous and a more appropriate phrase should be used in this document.	Donor payment practices at the centre should be reviewed against the requirements of Direction 0001. Compliant payment practices should be adopted and documented.	A review of the centre's SOP and discussion held with the centre's Director of Quality indicated that donor payment practices at the centre were compliant with requirements of Directions 0001. No further action required.
GN11: Donor recruitment Egg and sperm donors and providers are not investigated to assess their risk of suffering from prion	Donor screening processes and SOPs should include an assessment of their risk of suffering from prion disease.	A review of SOP A22 showed that this issue has been addressed. No further action required

disease, non-compliant with professional body guidance and thus CoP Guidance 11.15.		
G2: Staffing Activities related to WoC assessment and donor recruitment, assessment and screening are not specifically included in the clinicians' competence framework. In addition, no documentary evidence of staff competence assessment in these areas was available. This situation is non-compliant with SLCs T12 and T15a. It was also noted that the clinicians' competence framework was dated 09-April-2008, suggesting that document review processes are non-compliant with CoP Guidance 31.6.	The competence framework for clinicians needs to be reviewed and should include regular testing, at appropriate intervals, of clinicians' competence to undertake WoC assessment and donor recruitment, assessment and screening activities. Competence assessment activities should be effectively documented.	Documented evidence was seen of the competence framework for medical staff showing their competence to undertake WoC assessment and donor recruitment, assessment and screening activities. No further action required.
GN19: Traceability The centre is non-compliant with SLC T36 since recent audit of traceability processes has not been performed. The inspection team note that QI monitoring indicates that traceability processes have 'no known significant issues and risks' thus it is probable that there is little risk to patients associated with this non-compliance.	The centre should progress with their plan to audit traceability processes in 2011 to remove this non-compliance.	The report of a traceability audit performed in March 2011 was reviewed on inspection. No further action required.
GN31 Record keeping Training was said to have been recently provided to relevant staff regarding EDI data entry. The training provided was not documented in the staff training record reviewed.	All training provided to staff should be documented in staff training records.	This action has been implemented and evidence of this was seen during review of a training record for a member of the nursing team. No further action required.

Payment of HFEA invoices Between 1 March 2010 and 31 August 2010, the average payment time was 48 days, non-compliant with CH(10)02. The PR is thus non-compliant with SLC T9d.	The PR should review the HFEA invoice payment process to remove any barriers to payments being made within 28 days of the receipt of the invoice.	This financial year to date the centre is taking an average of 24 days to pay invoices which is an improvement of the 40 days average for the last financial year. No further action required.
Submission of data to HFEA The centre has made progress in clearing errors in EDI data. Numerous EDI records with errors still remain though. The non-clearance of these errors is non-compliant with Directions 0005, paragraph 4, which requires errors to be corrected within two months of them being identified.	The PR should ensure adequate staff and other resources are available to provide accurate data to the HFEA Registry and to clear errors in the historic data set in a manner compliant with General Directions 0005; paragraph 4.	At the time of this inspection The HFEA Registry reported that there were no issues with the centre regarding clearing errors in EDI data. However, with regards to the centre's success rate it was noted that there were issues with reporting of early outcomes within the required timeframe. Further action required.

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

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

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 centre has not validated all critical processes. SLC T72	The PR should ensure that all critical processes are validated. This validation may be based on studies performed by the establishment itself, data from published studies or from well-established processing procedures, or by retrospective evaluation of the clinical and laboratory results. An action plan to be submitted by the time the PR responds to this report.	The inspection report indicates that comprehensive validation for critical procurement and processing procedures which influence the quality and safety of gametes and embryos has been achieved. The minor processes for oocyte vitrification, assisted hatching, use of pentoxyfilline and use of enzymes post testicular biopsy are used very infrequently. **Action Plan** The protocol for validation of oocyte vitrification has been drafted and the process will be completed using literature reviews and actual process results. Protocols for the validation of assisted hatching and the use of & pentoxyfilline will be included in the VMP for completion in 2012. The requirement to use enzymes post testicular biopsy will be	The Executive is satisfied with the PR's response and will continue to monitor progress.

		discussed with the consultant urologist and included in the VMP for completion in 2012 if necessary.	
Semen analysis for initial diagnosis is performed at the centre. The laboratory is not currently accredited by CPA (UK) Ltd or another body accrediting to a similar standard. SLC T21,	The PR should ensure that laboratories who undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, obtain CPA (UK) Ltd or equivalent accreditation (NB. this includes the following disciplines: andrology; clinical genetics; haematology; bacteriology; virology; clinical biochemistry). The PR should submit a plan to the Executive documenting the estimated timeline for achieving compliance with this recommendation by the time the PR responds to this report.	As discussed during the inspection, the centre is in the process of obtaining accreditation to ISO17025 for semen and clinic science analyses; completion anticipated by the end of 2012. The Clinical Science lab has previously been subject to MHRA inspection and this has been confirmed as acceptable to HFEA. The classification of this finding as Major is considered by the centre to be excessive given that this requirement has not been flagged at previous inspections despite its inclusion in the Code of Practice. The embryology laboratory is licensed by HFEA; it participates in voluntary external QA	The Executive is satisfied with the PR's response and will continue to monitor progress.

		schemes for semen assessment and embryo grading, the reports of which are reviewed to assess both inter and intra centre results; semen analysis results are given by clinical scientists.	
Clear explanation of the reasons for transferring more than one embryo are not documented in patient's notes (Directions 0003).	The PR should ensure that a clear explanation of the reasons for transferring more than one embryo where the patient meets criteria for eSET are documented in the patient's notes. The PR should provide notice of this in his response to this report.	3 sets of patient records were reviewed during the inspection. All were found to record that a discussion took place with the patients regarding the risks of transferring of more than one embryo. One fully documented the reason for transferring two embryos. It is accepted that the other two records did not document the reason. It is also accepted that this is a major finding as it was raised as an issue at the previous inspection. Following the inspection, this point was raised with the Medical Director who has addressed this issue with the consultants responsible for	The Executive is satisfied with the PR's response and this issue will be subject to review at the time of the next inspection.

		embryo transfer. IDEAS has been amended to prompt consultants to provide a reason for transfer of 2 or more embryos.	
Should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born, the centre does not have a procedure in place to ensure that the nominated second parent is informed of the change in writing. (SLC T64(b)	The PR should ensure that should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent 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. The PR should provide notice of this in his response to this report.	The newly drafted "Legal Parenthood" SOP includes this requirement and will be issued by 19th January 2012. A copy of the draft document is appended for information. The classification of this as a major finding is not understood.	The Executive is satisfied with the PR's response and will continue to monitor progress. A review of the draft SOP appears to be satisfactory. The reason for this being classified as a major finding was because it was raised as an issue at the time of the last inspection in October 2010.
During the audit of treatment reporting, discrepancies were noted between the consenting decisions in the patient records regarding consent to the disclosing of identifying information to researchers and those entered on the HFEA register via (EDI	The PR should ensure the accuracy of data provided via the EDI system regarding consent to the disclosure of identifying information to researchers. This action should be completed by 19 January 2012.	All staff undertaking EDI input received training in the process during 2011 and have been reminded of the necessity for ensuring the data transfer is correct. A review of a sample of data will be undertaken by 19th January 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress.

SLC T41 & Direction 0005			
Not all licensed treatment cycles are being reported within the required timeframe via EDI to the HFEA. Direction 0005	PR should ensure all licensed treatment cycles are reported within the required timeframe to the HFEA. This action should be completed by 19 January 2012.	This classification of this as a major finding is not understood by the centre as the inspection report indicates that the submission of treatment forms against the treatments undertaken are considered to be satisfactory.	With regards to the centre's success rate it was noted that there were issues with reporting of early outcomes within the required timeframe. Also, reporting of treatment cycles was raised as an issue at the time of the last inspection in October 2010.
The centre does not have documented procedures describing recruitment, assessment and screening processes to be used for sperm and egg donors or providers in sperm sharing arrangements, non-compliant with SLC T33b.	The PR should ensure that the SOPs for the processes by which sperm and egg donors, and providers in sperm sharing arrangements, are recruited, assessed and screened, are finalised. This action should be completed by 19 January 2012.	This classification of this as a major finding is not understood by the centre as SOPs AD22 and AD4 detail the management (including recruitment / assessment and screening) of sperm and egg sharers / donors. Copies of these were provided to the inspection team.	The relevant SOPs reviewed during the inspection were under review and were due for completion by the end of the year. Procedures describing recruitment, assessment and screening processes were raised as an issue at the time of the last inspection in October 2010.

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
Witnessing of disposal of fresh embryos is performed but not explicitly stated in the centre's SOP (SLC T33(b).	PR should ensure that the witnessing SOP is updated to include disposal of fresh embryos. This action should be completed by 19 January 2012.	This requirement had been recognised by the centre and has been included in the new documents arising from the QMS review. This was demonstrated to the inspector during the inspection. The revised SOP will be completed by 19 Jan 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress.
The centre's procedure for withdrawing storage consent regarding the provision of a 12 month 'cooling off' period does not state that the 12 months period must not extend beyond the statutory storage period.	PR should ensure that the centre's procedure for withdrawing storage consent regarding the provision of a 12 month 'cooling off' period does state that the 12 month period must not extend beyond the statutory storage period. This action should be completed by 19 January 2012. The PR should provide notice	Action and timeframe agreed. SOP AD2 "Egg, sperm and embryo storage administration" is being updated as part of the QMS review and will include this requirement.	The Executive is satisfied with the PR's response and will continue to monitor progress.

	of this in his response to this report.		
There is only a draft counselling SOP in place. (SLC T33b).	PR should ensure that a counselling SOP is finalised. This action should be completed by 19 January 2012.	Action and timeframe agreed.	The Executive is satisfied with the PR's response and will continue to monitor progress.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting
13 January 2012

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

Minutes – Item 3

Centre 0100 (Bourn Hall Clinic) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Mark Bennett, Director of Finance & Facilities	Lauren Crawford

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 has been licensed since 1991. The current licence was issued on 5 July 2007.

2. The Panel noted that the premises have not undergone any major changes since the last inspection in October 2010.

3. The Panel noted that the centre offers a wide range of treatments including in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). The Panel also noted the centre conducts approximately 3000 treatment cycles per year.

4. The Panel noted that the centre's success rates for IVF/ICSI (June 2010 – July 2011) are in line with the national averages, with the following exceptions:

   - Frozen ICSI in patients aged <40 and 40+
   - and Frozen IVF in patients aged <40 and 40+.

   However, these exceptions may be due to the centre's failure to submit data on early outcomes.

5. The Panel noted that the centre's multiple pregnancy rate for 2010-11 for all cycles was 16 %.

6. The Panel noted that, at the time of the inspection, there were a number of areas that required improvement: seven major areas of non-compliance and three other areas of non-compliance or areas of poor practice.

7. The Panel noted that, since the inspection, the Person Responsible (PR), has provided evidence to the satisfaction of the Inspectorate that they are working towards fully implementing five major and three other areas of non-compliance or areas of poor practice.

8. The Panel noted that the PR has not given a response to two major areas of non-compliance or poor practice:

   - The PR should ensure that all licensed treatments cycles are reported within the required timeframe to the HFEA.
   - The PR should ensure that the standard operating procedures (SOPs) for the processes by which sperm and egg donors, and providers in sperm sharing arrangements, are recruited, assessed and screened, are finalised.

9. The Panel noted the Inspectorate's recommendation for the renewal of the centre's licence for a period of 4 years with no additional conditions.

10. The Panel confined its consideration to the evidence before it.

Decision

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

12. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

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

14. 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.

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

16. The Panel had regard to 'Guidance on periods for which new or renewed licenses can be granted' The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3. On the basis of the PR's responses to the inspection and the action taken on the major non-compliances, the Panel agreed that it had no concerns.

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

18. The Panel endorsed the recommendations in the inspection report for further action by the Person Responsible, and noted the PR's commitment to comply with the majority of these recommendations. The Panel urged the PR to respond to the Inspectorate on the two other major areas of non-compliance identified.

Signed: Peter Thompson Date: 23/1/12.
Peter Thompson (Chair)