Inspection Report

Date of Inspection: 16-17 October 2012
Purpose of inspection: Renewal of Treatment (including embryo testing) and Storage Licence
Length of inspection: 16 hours over two days
Inspectors: Wil Lenton (HFEA, Lead Inspector)
Andy Leonard (HFEA, Scientific Inspector)
Gill Walsh (HFEA, Clinical Inspector)
Chris Hall (HFEA, Audit)
Douglas Gray (HFEA, Observer)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 5 October 2011 and 15 January 2013.

Date of Executive Licensing Panel: 8 February 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 HFEA 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	The Centre for Reproductive and Genetic Health
Centre number	0044
Licence number	L/0044/15/L
Centre address	The New Wing, University College Hospital 256, Grays Inn Road, London, WC1X 8LD, UK
Person Responsible	Mr Paul Serhal
Licence Holder	Dr Joyce Harper
Date licence issued	01/04/2008
Licence expiry date	31/03/2013
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:

The Centre for Reproductive and Genetic Health is a re-designed facility within the Eastman Dental Hospital and has held a licence with the Human Fertilisation and Embryology Authority (HFEA) since 1990 with no additional licence conditions.

The centre offers a comprehensive range of assisted conception treatments to National Health Service Primary Care Trust commissioned and self-funded patients.

The centre currently provides in excess of 1500 licensed treatment cycles per year (including patient and donor insemination) and has one of the largest pre-implantation genetic diagnosis (PGD) programmes in the UK.

The Person Responsible (PR), Mr Paul Serhal, is registered with the General Medical Council (GMC), is on the specialist register for Obstetrics and Gynaecology and has completed the HFEA PR Entry programme (PREP number T/1025/7).

The last renewal inspection at the centre took place on 6 November 2007.The Licence Committee considered the renewal application on 28 January 2008 and issued the current licence, which expires on 31 March 2013. An interim inspection took place on 5 October 2011, during which one major area of non-compliance was noted, which the PR agreed to address.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 October 2011 - 30 September 2012 *
In vitro fertilisation (IVF)	719
Intracytoplasmic sperm injection (ICSI)	431
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	359
Donor insemination (DI)	111
Partner insemination	305**
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non-egg share)	20

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

*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.

** Partner insemination data for year 1 January to 31 December 2011(stimulated cycles).

Outcomes*
For IVF and ICSI, HFEA held register data for the period 1 May 2011 to 30 April 2012 show the centre's success rates are in line with or higher than national averages across all age groups and treatment types. For the year 1 January to 31 December 2011, the centre reported 305 cycles of partner insemination with 49 pregnancies, which equates to a pregnancy rate of 16%, which is consistent with the national average.

*The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision

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 generally discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises require further actions to make them suitable
- the practices are generally 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 a number of areas of practice that required improvement, including one critical area of non-compliance, nine major areas of non-compliance and seven other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and/or provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that any additional information requested by the Executive is supplied within agreed timeframes.
- All critical witnessing steps need to be contemporaneously signed off by two staff members.
- Critical transport conditions should be recorded when gametes/embryos are transferred between licensed centres.

Other areas of practice that require improvement:

- The witnessing standard operating procedure (SOP) and laboratory worksheets need to be reviewed and amended.
- The documented procedure for the recruitment, screening and reimbursement of sperm donors needs to accurately reflect current CoP 8 guidelines.
- Staff competence assessments need to be periodically undertaken and documented.

- A documented procedure for the dissemination of information to patients concerning legal parenthood needs to be developed.
- The 'bring-forward' system requires review.
- The requirement for additional patient/partner screening tests, in relation to high-risk patients should be clearly documented and implemented as and when required.

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

Critical areas of non compliance:

- **The PR should ensure that activities are carried out on suitable premises which are secure and restricted to authorised staff.**

Major areas of non compliance:

- The PR should ensure that the centre's multiple clinical pregnancy rate is carefully monitored and periodically reviewed in order to meet the HFEA's current multiple birth rate target.
- Any laboratory undertaking embryo biopsy assessment should be appropriately accredited.
- Data required to be submitted to the Authority should be reported both accurately and in a timely fashion.
- Consents for the disclosure of information to researchers should be reported accurately to the Authority.
- Audits of practice for all critical activities need to be undertaken.
- Further quality indicators (QIs) need to be developed.

Other areas of practice that require improvement:

- All third party agreements (TPAs) need to be evaluated as to their abilities to meet the required standards.

Recommendation to the ELP

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all or most recommendations made in this inspection report and further improvement is required in only a few areas of practice.

The PR instigated immediate remedial action in order to restrict public/patient access to sensitive areas within the centre, by fitting extra key-pad locks. Further remedial actions are currently in progress at the centre. The PR is to advise the Executive once all revised security measures have been implemented, at which point a re-visit to the centre will be arranged to review their enhanced security arrangements.

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 has a witnessing process in place, to ensure that all gametes and embryos, together with their associated patients/donors are contemporaneously identified and witnessed, at all critical points within the clinical and laboratory process. Apart from the two issues discussed below, a full witnessing record is kept within each patient's record, as confirmed via an on-site audit of ten sets of records. Witnessing sheets are audited on a monthly basis, as part of a regular audit of medical records undertaken at the centre. QIs for witnessing were seen to be in place (Standard Licence Conditions (SLCs) T71, T36 & T35). Documented records of the assessment of staff competence when performing witnessing tasks were seen (SLCs T33b & T12).
What the centre could do better. During the review of laboratory witnessing sheets it was observed that some were missing either one practitioner or witness signature and/or the time of witnessing. The witnessing of all critical steps during embryo biopsy and subsequent embryo use after biopsy is not contemporaneously witnessed (SLC T71). The present SOP covering the witnessing process and the supporting laboratory worksheets do not ensure that all critical points within the process are documented as being witnessed by two staff members (SLC T33b).

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.

Procuring, processing and transporting gametes and embryos
SOPs are in place describing all critical processes including those for procurement involving the receipt/transfer of gametes/embryos between HFEA licensed centres and the import/export of licensed material (SLC T33b).

Critical procurement and processing procedures were seen to have been audited against approved protocols, regulatory requirements and the centre's own QI within the last two years (SLCs T35 & T36).

Evidence of the validation of all critical equipment and processes involved in the procurement, processing and transport of gametes and embryos was seen during the inspection (SLCs T24 & T72).

Training folders observed in the course of the inspection demonstrated that staff competence to perform critical procurement processes was periodically assessed (SLC T15a).

Evidence was seen that clinicians document the justification for the use of patient gametes in treatment, or embryos created with their gametes, based on the patients' medical history and therapeutic indications (SLC T49).

It was established that all laboratory tests for patients are undertaken in a laboratory which has been certified by Clinical Pathology Accreditation (CPA) UK Ltd or another body accrediting to an equivalent standard (SLCs T21 & T51).

Counselling
Through interviews with staff including one of the counsellors, it was established that counselling is offered to all patients (HF&E Act 1990 (as amended), Schedule 3, S.3 (1)a) which, where necessary, incorporates information concerning legal parenthood issues (HF&E Act, Schedule 3Z part 2). A counselling SOP is in place and QIs for counselling have been developed (SLCs T33b & T35). An audit of the counselling service has also been performed, as was evidenced in quality audit meeting minutes from 13 September 2012 (SLC T36).

What the centre could do better.

Procuring, processing and transporting gametes and embryos
The checklist required to be completed for the transport of gametes/embryos between licensed centres was on occasion found to contain incomplete information, including temperature and witnessing signatures (SLC T107).

Donor recruitment, assessment and screening (Guidance Note 11)
Payments for Donors (Guidance Note 13)
Donor assisted conception (Guidance Note 20)

What the centre does well.

Donor recruitment, assessment and screening
From discussions with staff, a review of donor records and documentation seen on inspection, it was established that the centre generally recruits, assesses and screens gamete donors in line with current regulations, except for the issues mentioned below (SLC T52). A SOP is in place which describes the recruitment process (SLC T33b), audits of practice have been undertaken and QIs established for sperm donors (SLCs T36 & T35).

Screening tests are performed in an appropriately accredited laboratory (SLC T53a). Donated sperm samples are quarantined and re-tested in line with current regulations (SLC T53c). Upon request donors can be provided with information concerning the numbers, gender and birth year of all offspring born as a result of their donations (HF&E Act 1990 (as amended), Section 31ZD (3)).

Payments for Donors
Following a review of donor records, discussions with staff and from documentation seen during the inspection, it was established that payments to donors are compliant with current regulations (SLC T69).

Donor Assisted Conception
Evidence was provided that those who are to receive treatment with donated gametes or embryos are provided with information on the importance of informing any resulting child at an early age of their donor origins and how this may be best achieved (SLC T63).

Confirmation was given by the centre that where the provider of gametes, donated prior to April 2005, has not consented to being identifiable, the donated gametes and any embryos created with those gametes, are only to be used in treatment to achieve a sibling pregnancy (SLC T54).

What the centre could do better.

The sperm donor recruitment assessment and screening SOP did not follow current professional body guidelines concerning;

- the upper age limit for sperm donors (CoP Guidance 11.2; but see also 11.4)
- the need to re-screen for syphilis one month after the last donation (CoP Guidance 11.21)

The SOP for sperm donor reimbursements did not provide up-to-date details as applicable under General Direction 0001 version 3 (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)
- Intracytoplasmic sperm injection (ICSI) (Guidance Note 21)

What the centre does well.

Quality management system
The centre has a quality manager in post who maintains a quality management system (QMS), including a quality manual, training and reference materials, which underpins the centre's activities (SLC T33).

From discussions with staff, observation of practice and a review of documentation during inspection, it was found that generally SOPs are in place (SLC T33b) which direct all treatment service activities and, where relevant, specify any critical materials and reagents to be used (SLC T31). Except for the areas mentioned below, QIs are in place for the centre's critical activities (SLC T35) and audits of them have been conducted within the last two years (SLC T36). The centre is ISO 9001:2008 certified.

Traceability
From observation of practice, a review of patient / donor records and discussions with staff, it was seen that all gametes and embryos, and all equipment and materials which may come into contact with them and affect their quality and safety, are traceable from procurement to treatment or disposal. A SOP is in place specifying the processes by which traceability is assured (SLCs T22, T33b & T99). Traceability procedures are audited quarterly; non-conformities are identified, corrective actions implemented and any learning reported at the next departmental meeting (SLC T36). QIs for traceability have been developed and are evaluated during audit (SLC T35). Evidence of the periodic assessment of staff competence when performing traceability procedures was seen (SLC T15a).

Process validation
Critical procurement and processing procedures and all equipment used in these processes have been validated. Validation documents were available to view on inspection (SLCs T24 & T72).

Equipment and materials
Staff are alerted via alarms if equipment parameters breach defined limits (SLC T24). Equipment and materials used in service delivery are designated for their specific purpose and are regularly serviced and maintained (SLCs T23 & T26). SOPs are in place for the use of all critical equipment and include how to proceed in the event of malfunction (SLC T27). CE marked equipment and materials are used wherever possible (SLC T30).

Premises
A tour of the centre confirmed that all licensed activities are conducted in the licensed premises, with the exception of embryo testing (SLC T1). Air quality is comprehensively

assessed in critical areas and the laboratory background by monthly particle counting and measurement of room pressure differentials. A comprehensive annual functional assessment of HEPA filters, air-flow volumes and room pressure differentials, together with a full service/maintenance schedule of all work-stations ensures that the processing of gametes and embryos takes place in an environment of appropriate air quality (SLC T20).

Adverse incidents
The centre has an adverse incident SOP, documenting the procedure to follow in the event of an incident, including HFEA reporting requirements. Via review of the electronic incident log, it was determined that all required incidents have been reported to the Authority in accordance with current requirements (SLC T118).

Third party agreements
Following discussions with staff and document review it was established that the centre has written TPAs in place with all third parties providing goods and services, which may influence the quality and safety of gametes and embryos. The centre has a written agreement in place with the University College London NHS Foundation Trust Reproductive Medicine Unit (RMU) to provide a satellite IVF service, together with laboratory supervision of their IUI, semen analysis and sperm storage services. Both written agreements were last reviewed in April 2012 and are active until April 2013. There is a scheduled minuted meeting between CRGH and RMU management every two months, in order to review key performance indicators (KPIs) and any other arising issues. (General Direction 0010). The centre keeps a complete list of all current TPAs and the ones reviewed specified the terms, responsibilities and core requirements relevant to each party (SLCs T111; T113; T114 & T115).

Intracytoplasmic sperm injection (ICSI)
The centre has a SOP in place for performing ICSI (SLC T33b). QIs have also been developed and are evaluated during audit of ICSI practice (SLCs T36 & T35). QI monitoring data is reviewed as part of the periodic assessment of staff competence to perform ICSI; these assessments are documented (SLC T15a).

What the centre could do better.

Premises
During the tour of the centre's premises and facilities it was observed that;

- Public/patient access from the waiting area in the 'New Wing' to the rest of the centre was unrestricted due to unsecured double swing-doors leading out of the area.
- Public access to the lower ground floor patient recovery bay and theatre area was unrestricted from at least two unsecure doors. During the course of the inspection the inspection team was able to gain access to patient recovery bays and theatre areas via these unsecure doors.
- There was unrestricted access to the lower ground floor areas of the unit via an internal corridor leading to the Eastman Dental Hospital. This was graphically highlighted during the tour of the premises, where two members of the public, who had just visited the dental hospital, asked for directions concerning exits from the unit.

Thus several access points into and from the unit were found to be insecure during the present inspection, potentially giving unrestricted public/patient access to sensitive areas of the centre, which could directly affect patient safety, privacy and confidentiality as well as giving potential access to confidential patient records and licensed material (SLC T17; SLC T9b; HF&E Act 16; 2d).

Quality management system
No QIs are presently in place (SLC T35) for;

- the submission of data to the Authority
- the selection and recruitment of egg donors

Audits of practice have not been undertaken (SLC T36) for;

- PGD and PGS treatment provision
- submission of data to the Authority
- the selection and recruitment of egg donors
- the cryo-storage of licensed material

Third party agreements
The centre has not evaluated the ability of all third parties to meet all required standards set out in licence conditions and guidance (SLC T112).

The centre has not ensured that all TPAs include a condition requiring third parties to meet all relevant licence conditions and guidance specified in the HFEA CoP (SLC T116).

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 24%. This represents performance that is likely to meet the HFEA 20% live birth rate target.

For the time period April 2011 to March 2012 the centres multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%: this represents performance that is statistically likely to be greater than the HFEA 15% live birth rate target.

What the centre does well
The PR has provided sufficient evidence to demonstrate compliance with HFEA General Direction 0003 in that:

- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and the outcomes, which are also recorded in the patients' records.

What the centre could do better

On-going monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is likely to exceed the HFEA 2011/12 maximum multiple birth rate target of 15% (SLC T123).

Staff engaged in licensed activity

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

What the centre does well.

The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has many years of practical experience which is directly relevant to the activities to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1025/7).

From documentation reviewed, discussions with staff and observations made during the inspection, the inspection team concluded that the PR has generally carried out his duties appropriately. He has been pro-active in response to all identified non-compliances (SLC T9) and has also provided assurance that;

- staff are suitably qualified and are available in sufficient numbers to carry out all the services offered; workforce requirements have been reviewed within the last year (SLC T12);
- medical practitioners are registered with the GMC (SLC T14);
- nursing staff are registered with the Nursing and Midwifery Council (SLC T14);
- eligible scientific staff are registered with the Health Professions Council (SLC T14);
- all staff can show evidence that they are trained to carry out their designated tasks (SLC T15);
- all staff can show evidence of their competence to carry out their designated tasks (except for specific processes mentioned elsewhere in the report and which are currently being addressed) (SLC T12);
- staff have access to continuing professional development (CPD) (SLC T15);
- all medical activities are overseen by a medical practitioner (SLC T16);
- the centre's patients, their partners and donors have access to a suitably qualified counsellor (SLC T12).

What the centre could do better.

The PR must ensure that activities are carried out on suitable premises (SLC T9b).

Welfare of the Child (Guidance Note 8)

What the centre does well.

Following discussions with staff it was established that before providing treatment services, the centre makes an assessment of the welfare of the child (WoC) who may be born as a result of licensed treatment and of any other child who may be affected by that birth.

The centre has a documented SOP in place for when staff undertake a WoC assessment (SLC T33b).

Evidence was reviewed showing that at least 11 sets of medical records have been audited on a monthly basis for completion of WoC forms. The last audit, undertaken on 13 September 2012, discovered four discrepancies which were acted upon and resolved (SLC T36).

What the centre could do better.

No evidence was provided of the periodic assessment and documentation of clinical staff competence to perform a WoC assessment (SLC T15a).

Embryo Testing

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.

The centre conducts embryo biopsy for both pre-implantation genetic screening (PGS) and PGD. Biopsies are analysed by two genetics laboratories with whom the centre has TPAs (SLC T111).

A SOP is in place to direct embryo testing procedures, which has been validated against professional body guidance and published studies (SLCs T72 & T33b). Staff performing embryo biopsy procedures were able to provided evidence of training and the assessment of their competence to conduct this procedure (SLC T15(b)). QIs relevant to embryo testing procedures have been established (SLC T35) and the results are regularly audited as part of an annual practitioner performance review (SLC T36).

Staff were able to provided assurance that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, have been subject to genetic testing unless expressed authorised by the HFEA (SLC T88) and;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons (SLC T88b) and;
- biopsied embryos are not transferred into a woman in the same cycle of treatment as non-biopsied embryos (CoP; Guidance 10.4).

The centre ensures that people seeking PGS / PGD are given written information, are able to discuss the implications of their treatment and have access to clinical geneticists, genetic and infertility counsellors where required.

What the centre could do better.

One of the third party genetics laboratories which conducts the analysis of embryo biopsies is not accredited by CPA (UK) Ltd or equivalent, albeit equivalent accreditation is being sought (SLC T21).

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.

Treating patients fairly
From discussions with staff and observations made on inspection, the centre ensures that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well being of all prospective and current patients and donors. Patient feedback questionnaires are used to inform the centre about any patient issues which could be improved upon as part of the QMS.

Confidentiality and privacy
Apart from the security issue concerning access to the unit discussed elsewhere, it was determined that staff appeared to understand the need to maintain patient confidentiality and privacy, have received training in this area, and keep all confidential information secure when not in use (SLCs T43; T44 & T45).

Complaints
The centre actively seeks patient feedback and investigates and learns from patient complaints. A complaints policy is located within the patient waiting area. Staff stated that they always attempt to resolve patient issues locally in the first instance by private discussion. If this is not possible the issue is escalated in line with the complaints procedure (SLC T33b). The complaints log was reviewed and found to be compliant with CoP Guidance 28.7.

Provision of costed treatment plans
Prospective patients are invited to regular open evenings attended by staff members from all disciplines and a generic treatment information pack is provided to prospective patients prior to the first consultation. A current treatment price-list is provided to all prospective patients via the information pack and is available in the patient waiting area. Staff stated

that the cost of any required drugs is also discussed with the patients prior to any treatment, storage or both being offered (CoP Guidance 4.3).

Egg sharing arrangements
Staff stated that very few egg-sharing treatments are provided at the centre, but that they do have documented procedures in place for its provision (SLC T33b). The egg providers in egg share arrangements are screened as donors, in accordance with SLCs T52 and T53 and current professional guidelines; they are also registered with the HFEA as donors. Egg-share patient records reviewed demonstrated that the required screening tests had been undertaken, counselling offered and relevant consents completed, prior to treatment.

Records reviewed and discussions with staff confirmed that treatment is only provided to the egg sharer in the course of the donation cycle unless there is a documented medical reason as to why treatment cannot be provided at that time (General Direction 0001 version 3).

Surrogacy
The centre provides surrogacy treatment as and when required and has documented procedures in place (SLC T33b). The centre screens all gamete providers in surrogacy arrangements as registered donors and in line with current professional body guidelines (SLCs T52 and T53).

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)
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

From discussions with staff, documents reviewed and information provided prior to inspection, it was established that prior to the signing of consents and before treatment services are provided, prospective patients and their partners, and donors, are supplied with information (SLC T58) relating to;

- the nature of any treatment provided,
- any consequences/risks of treatment,
- any analytical tests required,
- confidentiality,
- the giving and withdrawal of consent, and
- the availability of counselling.

There is a SOP in place for this process (SLC T33b). Staff complete a checklist of information provided to patients, which was observed during the inspection (HF&E Act Schedule 3; 3(1b)). An audit of 11 sets of medical records undertaken on 13 September 2012 confirmed that appropriate, accurate and up-to-date information had been provided

to patients, prior to the signing of consent forms (SLC T36).

An audit of patient information provided on the centre's website was undertaken which showed the information content to be compliant with Chair's Letter CH(11)02.

Legal Parenthood
A documented procedure was seen to be in place describing the process to follow if a woman being treated withdraws her consent to a nominated second parent being the legal parent to any child born, which included the need to inform the nominated second parent of the consent withdrawal (SLC T33b).

What the centre could do better.

Legal Parenthood
Staff stated that information concerning legal parenthood was discussed with patients as part of the consent process, but that no formal documented procedure was in place (SLC T33b).

No evidence of the periodic assessment and documentation of clinical staff competence when providing information to patients (including legal parenthood) prior to consent was provided (SLC T15a).

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.

From discussions with staff, documents reviewed and information provided prior to inspection, it was established that effective written consent is obtained from patients prior to any treatment being offered and that the centre has a documented SOP in place for this process (SLC T33b). A monthly notes audit is undertaken to determine that effective written consent has been taken (SLC T36). QIs were seen to be in place (SLC T35). Patients are never asked to sign consent forms on the day of treatment (HF&E Act Schedule 3; 3; 1a). The identity of the person giving consent is verified at the time of signing by photographic evidence (CoP Guidance 5.10 and 5.11). Staff understood the legal parenthood issues and there was a procedure in place on occasion that such consent is withdrawn (SLCs T64, T65 and T33b).

What the centre could do better.

No evidence was provided of the periodic assessment and documentation of clinical staff competence to take patient consent (SLC T15a).

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.

Discussions with the PR 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 or at third party premises (SLC T1).

Observations and discussions with staff on inspection indicated that all staff at the centre have respect for the special status of the embryo when carrying out assisted conception treatment services. Only permitted embryos are created and used in the provision of treatment services and the medical reasons for treatment were seen to be recorded in all patient records reviewed on inspection (SLC T49).

Donor compensation
The centre keeps a record of all reimbursements made to donors via an in-house form. Evidence was provided that all money and other benefits given or received for the supply of gametes or embryos are compliant with General Direction 0001 version 1.

What the centre could do better.

Nothing noted

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17)

What the centre does well.

From discussions with staff and the review of documentation, it was established that the centre has a documented SOP in place for cryopreservation of gametes and embryos (SLC T33b). Staff competence to perform cryopreservation has been assessed and documented (SLC T15a). Except for the issue mentioned below, before any material is stored the gamete providers are screened in accordance with regulatory requirements (SLC T50). All screening tests are performed in an appropriately accredited laboratory (SLC T51a). Storage procedures have been validated (SLC T72) and are subject to QI monitoring (SLC T35).

All currently stored licensed material is within its consented storage period (HF& E Act 1990 (as amended) Section 14(1)c).

What the centre could do better.
Although the centre operates a bring-forward system in order to monitor licensed material which is approaching the end of its consented storage period, it was found that the present system occasionally doesn't allow staff enough time to undertake all required actions. (CoP Guidance 17.18).

The centre did not provide evidence of any cryo-storage audit (SLC T36).

Gamete providers, or their partners, who have lived or originate from geographical locations with a high incidence of HTLV-1, are not regularly screened for this virus, prior to their gametes being stored (SLCs T50c & T33b).

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.

Distribution of gametes and embryos
From discussions with staff, review of documentation and observation of practice it was established that the centre has procedures in place to ensure gametes and embryos are distributed under conditions that protect their safety and quality (SLCs T33b; T105; T106; T107 & T108). During the transport of licensed material between licensed centres, appropriate documentation is transferred with the gametes and embryos (SLCs T109 & T110). Before any material is stored the gamete providers are screened in accordance with current regulatory requirements, except for the issue mentioned above (SLC T50). The centre has a procedure in place for the recall of transported material. A TPA is in place with the courier used to transport cryostored material, which specifies transport conditions to be maintained during transit (SLC T107; CoP mandatory requirements 15B).

Import and export of gametes and embryos
Through discussions with staff and documentation review, it was found that since the last inspection the centre had imported 53 ampoules and 73 straws of sperm, 83 eggs and five embryos, in accordance with General Direction 0006. During the same time frame it exported eight embryos in accordance with General Direction 0006.

What the centre could do better.

Distribution of gametes and embryos
The checklist required to be completed for the transport of gametes/embryos between licensed centres was on occasion found to contain incomplete information, including temperature and witnessing signatures (SLC T107).

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

Through documentation review, it was established that embryos are only used for authorised training activities after consent has been obtained from the gamete providers; embryos used in training are not subsequently used for patient treatment (SLCs T92; T93 & T94). Prior to providing consent for use of embryos in training, gamete providers are provided with all required information by an appropriately trained member of staff (SLCs T97 & T98). Centre staff ensure that clinical and training roles are separated (SLC T95). Audits of practice are in place for this process (SLC T36).

What the centre could do better.

Nothing noted

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.

Patient records reviewed during the inspection were seen to be well organised, clear, legible, and appeared to include all relevant patient information (SLCs T39 & T46).

To confirm that data submitted by the centre for inclusion on the HFEA register accurately reflects that found in source records on-site, a sample of 42 assorted form type data submissions were reviewed against source documentation held in patient and donor files. No critical errors or omissions were found in the data that would prevent the Authority fulfilling its statutory obligations, except for the sole unreported DI treatment referred to below. Additionally no systematic errors were identified within the sample.

To determine whether all licenced treatment activity is reported to the HFEA within required timescales, a sample of treatments recorded within the centre's laboratory spread-sheets were compared to data submitted by the centre for inclusion on the HFEA register. All 128 IVF treatments and 111 of the 112 DI treatments in the audit sample had been notified to the HFEA by the date of inspection.

What the centre could do better.

One piece of licenced treatment data that the Authority is required to hold on its register had not been provided by the centre at the time of inspection (i.e. one of the 112 DI treatments in the audit sample). Failure to notify the Authority of treatment cycles involving donor gametes potentially impacts on its ability to fulfil statutory obligations to donors and the donor-conceived (General Direction 0005).

21% of DI cycles and 29% of IVF cycles in the audit sample were reported to the HFEA in excess of the five working day period required by General Direction 0005.

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 information as required by the licence renewal application process prior to inspection. All members of staff cooperated fully with the inspection team during the on-site visit.

On the licence renewal application form, the PR indicated that the centre plans to introduce two new laboratory techniques as part its licensed treatment activities. On further discussion with the PR and centre manager it was established that both 'in vitro maturation' and 'transport of eggs' were presently only at the literature search stage, and would not be introduced in the near future.
The PR is reminded to keep the Executive informed about any future developments at the centre and to notify the Authority, via the clinic portal, when any proposed new activity has been fully validated and competent, trained staff are in place to safely deliver any such new activity (General Direction 0008 (18)).

What the centre could do better.

Additional information requested post-inspection by the Executive was not supplied within agreed timeframes (SLC T9c).

There was one outstanding issue from the previous interim inspection undertaken on 5 October 2011 (concerning the audit of consents to information disclosure to researchers), which had not been fully implemented from the previous inspection. The quality manager was able to demonstrate at this inspection, that 60 random sets of patient's consents to disclosure to researchers, documented between October 2011 and September 2012, had been retrospectively audited between 5-12 October 2012; all relevant corrective actions had been undertaken (SLC T36). On-going monthly patient records audits are now in place to identify any other similar discrepancies.

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
Apart from the security issue concerning access to the unit discussed elsewhere, it was established that the centre ensures that all information about people having treatment, donors and children born as a result of assisted conception services, is kept confidential and is only disclosed in circumstances permitted by law (SLC T43).

Centre staff undertake initial training concerning privacy and confidentiality (SLC T15(a)(d)).

Processes are in place to ensure that access to the centre's health data and records are kept secure at all times and only made available to either people named on the centre's licence or as authorised by the PR (SLC T44).
What the centre could do better. **Consent to treatment, storage, donation and disclosure of information** To determine whether the register properly reflects the consent given by patients and their partners for the use of register information for research purposes, a sample of 10 completed patient and partner disclosure consents were reviewed against disclosure consent data supplied by the centre for inclusion on the HFEA register. A discrepancy was found between two of 10 patient and partner completed disclosure consents in patient files compared to consent data recorded on the register. Both instances relate to a patient and her partner who completed new disclosure consent forms when they returned for treatment following a two year gap, but where, due to erroneous data being supplied by the centre, the register has not been updated to reflect that consent for use of register data by researchers has been given (General Direction 0007; Chair's Letter CH(10)05).

5. Changes / improvements since the previous inspection on 5 October 2011.

Area for improvement	Action required	Action taken as evidenced during this inspection
An audit of five patient records all contained consent forms completed by both patient and partners, however, one had not been completed properly and in two records the consent to disclosure to researchers in the patient records did not match the information held by HFEA Standard Licence Condition T9 (e). Directions 0005, paragraphs 8 and 9	The PR should ensure that all consent forms for the disclosure of information to researchers are completed correctly, entered onto the HFEA register and completed accurately Immediately The PR should audit the consent to disclosure of information to researchers in the patient records against the consent decisions which have been submitted to the HFEA via the HFEA electronic data interface (EDI). This audit should encompass all patients for whom consent to disclosure has been submitted over the EDI system. The Executive recognises that this audit will be time consuming and recommends completion by January 1st 2012 and a report submitted to the Executive on the same date.	The quality manager was able to demonstrate that a retrospective audit of 60 random sets of patient's consents to disclosure of information to researchers, completed between October 2011 and September 2012, had been audited between 5-12 October 2012 and that all relevant corrective actions had been undertaken. Although the previous inspection recommendation had not been fully implemented, the inspector is reassured that the current audit practice of an on-going monthly review of patient records is sufficiently robust to identify any similar discrepancies going forward. No further action required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions 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
Several access points into and from the unit were found to be insecure, potentially giving un-restricted public/patient access to sensitive areas of the centre. **SLC T17** **SLC T9b** **HF&E Act 16; 2(d).**	**The PR should undertake a thorough risk assessment of the premises and facilities in order to determine if any additional security measures are required to ensure that patients are safe and that licensed material and confidential information are kept secure at all times.** **The risk assessment should be undertaken**	A thorough risk assessment has been completed. Following this assessment we have already had key pad locks fitted to all doors which were safe to do so. Part of the risk assessment highlighted that several of the doors which required physical security measures were fire exits and as such required an electronic locking mechanism wired in to our fire alarm system. We have already received one quote for this work and the second inspection and subsequent quote is due for December 11th 2012. We will inform the HFEA both once we have our date for installation and once the new measures have been fitted and tested.	The PR responded immediately by undertaking a risk assessment and has addressed some of the security issues highlighted within the report. The Executive will await further communication from the PR concerning the outstanding security issues, prior to arranging a follow-up

	immediately and the outcome/conclusions made available to the inspector at the PR's earliest convenience. **A further on-site visit to be arranged by the Executive once remedial actions have been implemented to restrict any potential unauthorised public/patient access to sensitive areas within the centre.** **Even though the centre has thus far experienced no incidents relating to this issue, the PR should be aware that a licence can be revoked if the Authority ceases to be satisfied that the premises specified in the licence are suitable for the licensed activities.**		visit to the centre. **Further action required**

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
Additional information requested post-inspection by the Executive was not supplied within agreed timeframes. SLC T9c	The PR should ensure that centre staff cooperate fully with the Executive and that any additional information is supplied within agreed timeframes. All outstanding requested information relating to the inspection should be forwarded to the Executive without further delay.	We apologise for any delays. We have reminded all staff about the importance of timely communications and this will be monitored formally going ahead as part of our increased audit plan.	Issue resolved. No further action required.

The centre's current multiple pregnancy rate is such that it is significantly likely that the centre will not meet the HFEA year three target rate for multiple births of 15%. SLC T123	The PR should ensure that centre staff continually monitor treatment outcomes and the effectiveness of their current MBMS policy, in order to determine whether any further adjustments are required. To be implemented immediately. Any additional actions taken by the centre should be communicated to the Executive. This issue will be subject to on-going monitoring by the Executive through the HFEA risk tool.	The MPR is already closely monitored within our system. To further improve our monitoring and improvement we have now added this as a standing agenda item on the monthly lab performance meeting, the internal quality dashboard and the monthly doctors meeting.	This issue is being addressed by the PR. The centre's MPR will be closely monitored by the inspector on a monthly basis via the HFEA Risk tool. **Further action required**
Data required to be submitted to the HFEA and held on its register of information is, in some cases, either not being reported or is being submitted late.	The PR should ensure that any data which the HFEA is required to hold on its register is provided within the timeframe specified in General Direction 0005. The process for submitting	This aspect has now been added in to our new ISO audit schedule with the results being presented monthly at the lab performance meeting chaired by the quality manager	This issue is being addressed by the PR. This will be closely monitored by the inspector via the monthly HFEA Risk tool and liaison with the

SLC T9e; General Direction 0005.	licensed treatment data to the HFEA should be reviewed and, where applicable, improved to ensure that licensed treatment activity is reported to the Authority within the given timeframes. This should be implemented immediately and the actions taken reported to the Executive by 17 January 2013. This issue will also be monitored by the inspector via the HFEA risk tool.		Register team. **Further action required**
The consent to disclosure of information to researchers is not being reported accurately in some cases. General Direction 0007; Chair's Letter CH(10)05	The PR should ensure that any information concerning the disclosure of information to researchers is reported accurately to the Authority. The PR should undertake an audit of the last three month's submissions of such information to the Authority, against the original patient consents, to identify any reporting errors	We have implemented a new system to ensure that data is always double checked by a member of staff independent from the initial doctor prior to submission of data. The audit will be completed and forwarded prior to January 17th 2013 as requested (we are postponing the audit so that we can audit three full calendar months of data which is different to the results of the audit already presented).	This issue is being addressed by the PR. The Executive will await the audit results due on 17 January 2013. **Further action required**

	and to ensure that the reporting process is robust going forward and to be certain that all subsequent information is being reported accurately. A summary of the audit should be forwarded to the Executive by 17 January 2013.		
During the review of laboratory witnessing sheets it was observed that some were missing either one practitioner or witness signature and/or the time of witnessing. The witnessing of embryo biopsy and subsequent embryo use after biopsy is not being contemporaneously witnessed by two centre staff. SLC T71.	The PR should ensure that all critical processing steps involving gametes and/or embryos, are contemporaneously witnessed and documented by two staff members. To be implemented immediately; an update of actions taken should be forwarded to the Executive by 17 January 2013.	Our SOPs have been updated and changes cascaded to staff. All containers containing gametes or embryos are labelled with two identifiers and double witnessed during all critical steps. All procedures in the lab are double witnessed. The primary embryologist carrying out the procedure signs for the process carried out and the witness checks all the details as per the SOP (LP076).	Issue addressed and resolved by the PR. This practice will be reviewed at any subsequent inspection. No further action required.

One of the laboratories that perform PGD testing is not accredited by Clinical Pathology Accreditation (CPA) UK Ltd or an alternative body accrediting to an equivalent standard. SLC T21.	The PR should obtain evidence from the PGD laboratory of appropriate accreditation, or in its absence should determine their plans to obtain appropriate accreditation (e.g. ISO 17025). An update to be forwarded to the Executive by 17 January 2013.	One of the labs which undertakes PGD testing for us is based in Rome, Italy (Genoma) and is accredited to ISO 9001:2008. We are waiting on a full response regarding more appropriate registration such as a CPA alternative or ISO 17025. We will send the full response to the Executive by January 17th 2013 as requested.	This issue is being addressed by the PR. Further information to be forwarded to the Executive by January 17 2013. **Further action required**
The checklist required to be completed for the transport of gametes/embryos between licensed centres was on occasion found to contain incomplete information, including temperature and witnessing signatures. SLC T107.	The PR should make certain that the checklist of actions undertaken by staff, when transporting gametes/embryos between licensed centres, is completed appropriately and signed off where applicable. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	The checklist for transferring samples between clinics (internal form LF057) has been amended. The changes include the requirement of countersigning of the completeness of the checklist prior to dispatch or receipt of samples together with the latest version of the general directions governing the import and export of gametes and embryos.	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection. No further action required.
QIs are not in place for the following centre	The PR should ensure that QIs are developed for all	Quality indicators are now in place and will be audited each month starting from January 2013.	This issue is being addressed by the PR.

activities; • recruitment, assessment and screening of egg donors • submission of data to the HFEA SLC T35.	critical activities. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.		The PR should forward the results of the first three monthly audits undertaken in 2013 to illustrate how QIs are being evaluated. **Further action required**
Audits of practice have not been undertaken for the following centre activities; • recruitment, assessment and screening of egg donors • submission of data to the HFEA • the cryo-storage of licensed material • the provision of PGD/PGS SLC T36.	The PR should ensure that audits of practice are undertaken for all critical activities. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	We have now developed a more comprehensive audit schedule in line with ISO 9001:2008 requirements. This new audit schedule will take effect from January 2013 onward.	This issue is being addressed by the PR. The PR should forward the results of the first three monthly audits undertaken in 2013 to illustrate how the new schedule is working. **Further action required**

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
The present SOP covering the witnessing process and the supporting laboratory worksheets do not ensure that all critical points within the process are documented as being witnessed by two staff members. SLC T33b	The PR should ensure that the SOP covering the witnessing process and supporting laboratory worksheets are reviewed/amended in order that all critical points within the process are documented as being witnessed by two staff members. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	All SOPs and clinical checklists have been reviewed and amended. The new process now ensures that all critical points are witnessed by two members of our staff.	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection. No further action required.
No formal documentation is in place which records the periodic assessment of the competence of medical staff to perform; • WoC assessments	The PR should ensure that formal documentation is in place, which records the periodic assessment of the competence of staff when undertaking all critical	We have a comprehensive clinical competency process as detailed in internal documents HRM49, HRM80, HRM91, HRM92, HRM146 and HRM147. Furthermore, we also have an external assessor visit the unit annually for an impartial assessment of clinical competence	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection.

• taking patient consent • provision of information • legal parenthood SLC T15a.	activities. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	(forming part of the annual appraisal process) in addition to the abovementioned in house competency assessment.	No further action required.
The centre has not evaluated the ability of all third parties to meet the required regulatory standards set out in CoP 8th edition. SLCs T112 & T116.	The PR must ensure that all third parties, providing goods or services that influence the quality and safety of gametes and embryos, are regularly evaluated as to their abilities to meet the regulatory standards set out in the CoP 8th edition. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	Our General Manager has recently achieved ISO lead auditor level and has advised us that this is an essential requirement of ISO 9001:2008 (section 7.4.1). As such, a formal review of all SLAs and TPAs is scheduled for January against both the CoP criteria and our defined requirements. This will then occur annually in January.	This issue is being addressed by the PR. Further information to be forwarded to the Executive once all reviews have been completed. **Further action required**
The SOP for sperm donor recruitment, screening and reimbursement	The PR must ensure that the SOP for sperm donor recruitment, screening and	The current practice for reimbursement of donor expenses is in line with the CoP 8 as detailed in internal documents CPA101 and CF047. The	Issue addressed and resolved by the PR.

contains information which does not reflect current regulatory requirements. General Direction 0001 v3. SLC T33b.	reimbursement are reviewed/amended in order that they reflect current regulatory requirements. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	checklists have been updated to reflect the clinical practice. The age limit of the sperm donation has been revised as 41. Furthermore, the screening of sperm donors has been updated in accordance with published guidelines.	This issue will be reviewed at any subsequent inspection. No further action required.
There is no SOP in place for the dissemination of information to patients concerning legal parenthood. SLC T33b.	The PR should ensure that a documented procedure is in place for the dissemination of information to patients concerning legal parenthood, which includes actions to be taken in the event of consent to a nominated second parent being the legal parent being withdrawn. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	SOP has now been written and implemented and the relevant patient information has been updated.	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection. No further action required.

The centre's bring-forward system doesn't allow staff enough time to undertake all required actions (CoP Guidance 17.18).	The PR should make certain that the centre's bring-forward system is reviewed/amended to ensure that staff have sufficient time to undertake all required actions. The PR should ensure that the required actions are implemented by 17 January 2013 and the details of any actions taken are forwarded to the Executive.	The bring forward system for the invoicing and tracking of consent expiry has been amended to start contact at 3 months, 2 months and 1 month prior to expiry. All letters sent would be recorded delivery. Any patient not having responded within the last month pending would initiate the laboratory tracing the patients details via the GP and the Health Authority if applicable (CPA 019). At all times email and phone contacts would be made to establish contact with the patient	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection. No further action required.
Gamete providers, or their partners, who have lived or originate from geographical locations with a high incidence of HTLV-1, are not regularly screened for this virus, prior to their gametes being stored (SLCs T50c & T33b).	The PR should ensure that the requirement for additional screening tests, in relation to high-risk patients (and their partners) are clearly documented in clinical SOPs and are implemented as and when required. The PR should ensure that the required actions are implemented by 17 January	SOP's and clinical checklists are already in place. Current regulations as detailed in the SOPs and clinical checklists have been further highlighted in this context to staff. For further information, we can send the relevant checklists and SOPs to the Executive should you so desire (reference CL003, CL004, CL011, CL012, CL013 and CL016).	Issue addressed and resolved by the PR. This issue will be reviewed at any subsequent inspection. No further action required.

	2013 and the details of any actions taken are forwarded to the Executive.		

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

19 February 2013

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

Minutes – Item 1

Centre 0044 – (The Centre for Reproductive and Genetic Health) – Update to Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Hannah Darby, Senior Policy Manager Rachel Hopkins, Head of Human Resources	Neil McComb Observing: 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 a renewal inspection took place in October 2012, and a report was presented to the Executive Licensing Panel (ELP) on 8 February 2013, which adjourned until more information was provided to it. The Panel also noted that an updated executive summary was presented to the ELP on 15 February 2013.

2. The Panel noted the executive summary which explained that the outstanding remedial actions relating to the integration of the fire doors within the fire alarm system do not directly impact on the security of the premises.

3. The Panel noted that the Inspectorate was satisfied that the centre's premises are now suitable.

Decision

4. 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.

5. The Panel was satisfied that the application designates an individual to act as the Person Responsible (PR) and was satisfied that the designated PR is a suitable person to hold a licence.

6. The Panel was satisfied that the qualifications and character of the PR are 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, and has more than two years practical experience.

7. The Panel was satisfied that the licence renewal application does concern treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

8. The Panel was satisfied the PR possesses the formal academic qualifications set out in section 16(2) (c) (i).

9. The Panel was satisfied that the PR has at least two years practical experience which is directly relevant to the licenced activity.

10. The Panel was satisfied that the licence renewal application does concern the storage of gametes and embryos not intended for human application.

11. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licenced activities.

12. The Panel was satisfied that the application does involve the use of embryos for training. The Panel had regard to its embryos for training

decision tree and was satisfied that the requirements of paragraph 1 (3) and (4A) of Schedule 2 to the Act had been satisfied.

13. The Panel had regard to 'Guidance on periods for which new or renewed licences 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 recommendations made by the Inspectorate and the PR's response to them, the Panel agreed that it had no concerns.

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

Signed: Date: 27 February 2013
Juliet Tizzard (Chair)