Inspection Report

Date of Inspection: 15 and 16 January 2013
Purpose of inspection: Renewal of Treatment (including embryo testing) and Storage Licence
Length of inspection: 15 hours
Inspectors:

Janet Kirkland	(Lead inspector)
Victoria Lamb	(Scientific inspector)
Victoria Mills	(HFEA observer)
Gill Walsh	(Clinical inspector)
Chris Hall	(Register team)
Roup Kaur	(Register team)
Ted Webb	(Department of Health observer)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 21 March 2012 and 10 April 2013.

Date of Executive Licensing Panel: 26 April 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 Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence 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:	Guys Hospital
Centre number:	0102
Licence number:	L/0102/14/e
Centre address:	Assisted Conception Unit, 11th Floor Tower Wing, Guy's & St Thomas' Hospital NHS Trust, London, SE1 9RT
Person Responsible:	Mr Yacoub Khalaf
Licence Holder:	Dr John Scoble
Date licence issued:	01 July 2008
Licence expiry date:	30 June 2013
Additional conditions applied to this licence:	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre is part of Guy's & St Thomas' Hospitals NHS Foundation Trust and provides a full range of licensed treatments to NHS and self funded patients from London and the surrounding areas. The unit has an active research programme for which there is a separate HFEA Research Licence in place. The centre also provides a comprehensive pre-implantation genetic diagnosis (PGD) service and is the primary centre in a satellite agreement with The Leeds Centre for Reproductive Medicine (0314) and Jessop Fertility (0196) in Sheffield for patients who require PGD.

This centre has been licensed by the HFEA since 1992. The current Person Responsible (PR), Mr Khalaf, has been in post since April 2004 and is appropriately qualified for the role. Mr Khalaf has completed the PR entry programme (PREP) certificate number T/1059/7.

Activities of the Centre:

Type of treatment	Number of treatment cycles for 01 Jan 2012 - 31 Dec 2012
In Vitro Fertilisation (IVF)	688
ICSI	1493
GIFT	0
FET	562
DI	57
Egg share provider (sharer)	0
Egg share recipient	0
Egg donation (non egg share)	34

Other licensable activities	✓
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	✓

Outcomes*

For IVF/ICSI, HFEA held register data for the period October 2011-September 2012 show the centre's success rates are in line with national averages.

For the year 2011 the centre reported 97 cycles of partner insemination with 13 pregnancies. This equates to a 13 % pregnancy rate 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 whether he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The 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 one major area of non-compliance and four other areas of non-compliance or areas of poor practice.

Since the inspection visit the PR has confirmed and provided evidence that all of the following recommendations have been implemented.

Major areas of non compliance:

- The PR should ensure that donor registration information is provided to the Authority in accordance with the requirements of Directions 0005.

'Other' areas of practice that require improvement:

- The PR should ensure that different individuals are registered with the HFEA with unique patient/donor numbers.

- The PR must ensure that the bring forward system is effective in providing adequate opportunity for patients to extend consent before the expiry of existing consent.

- The PR should either ensure that the tubes are appropriately labelled during egg collection, or should ensure the practice is risk assessed.

- The PR should review the procedures for checking and submitting consent to disclosure decisions to the HFEA. The PR should audit a sample of patient and partner consents to disclosure of identifying information to researchers documented in patient records, against the consent decisions recorded in the HFEA Register, to determine whether the consent discrepancies between these sources noted on inspection are isolated occurrences or are more prevalent.

The committee is asked to note that the PR submitted an application for the renewal of a treatment and storage licence but that the PR subsequently confirmed in writing that he was applying to renew the centre's licence for treatment (including embryo testing) and storage.The inspection team recommends the renewal of the centre's licence for treatment (including embryo testing) and storage for a period of four 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.

All samples and the patients to whom they relate are identified and witnessed contemporaneously and a record of the manual witnessing checks is kept in the patient / donor's medical record, as confirmed by witnessing procedures observed and by a review of patient records seen on inspection (Standard Licence Condition (SLC) T71).

The inspection team were informed that the identity of each patient/donor is confirmed prior to each procedure both verbally and with reference to photographic identification and a signature check against the original signature in the patent's file.

The centre uses an electronic witnessing system to ensure the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process and to ensure that patients receive treatment using the correct gametes or embryos. A manual witnessing system is used for witnessing steps not covered by the electronic system such as the mixing of gametes, injecting sperm into eggs and the movement of gametes and embryos to or from cryo-storage (Code of Practice (CoP) Guidance 18.33).

The scientific inspector observed two sperm preparation procedures and one oocyte collection, all of which were witnessed in accordance with the centre's Standard Operating Procedure (SOP) and SLC T71. An audit of five patient records on inspection confirmed that records of manual witnessing are maintained in patient files. The centre does not keep a paper copy of electronic witnessing records in the patients' records but the laboratory manager provided assurance that the relevant electronic records are maintained and can be accessed if required. While this is non-compliant with the requirements of SLC T71 this omission is not considered a risk and no recommendations have been made in respect of this non-compliance.

The laboratory manager explained that should the electronic witnessing fail or not occur, the system will alert the user to this and the procedure would not continue until proper

witnessing steps are undertaken electronically or manually.

The centre has established quality indicators (SLC T35) relevant to witnessing and documented audits of witnessing procedures were seen on inspection. Where required, corrective actions have been recorded and implemented (SLC T36).Staff competencies for witnessing are documented and were seen on inspection (SLC T15 (a)).

What the centre could do better.

The tubes used during egg collection are not marked with patient identifiers (SLC T101). The tubes are used to transfer eggs within follicular fluid from the patient in theatre to the adjoining laboratory. The aspirate is then transferred to dishes marked with appropriate patient identifiers. Centre staff consider that there is no risk of misidentification because only one patient's gametes are processed in the critical work area at a time and the area is cleared after each patient's gametes are processed. This "clearing step" was seen to be included in the SOP and documented on a check list.

► **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 of gametes and embryos: (Guidance Note 15)
All critical procurement and processing procedures have been validated and documented in SOPs (SLC T72 T33(b)).

Quality indicators and objectives relevant to procurement and processing procedures have been established. Documented audits of these procedures were seen on inspection and where indicated corrective actions and their implementation had been documented (SLC T35 and T36).

Documented evidence of the assessment of competence for relevant staff in procurement and processing procedures was seen on inspection (SLC T15(a)).

Prior to processing, the providers of gametes intended for use in treatment or storage are screened in accordance with SLC T50 by a laboratory with Clinical Pathology Accreditation (SLC T21 and T51).

An audit of six patient files conducted on the day of the inspection confirmed that the justification for the use of patient's gametes or embryos created with their gametes is documented (SLC T49).

There are SOPs in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution and also a recall procedure for handling returned gametes and embryos (SLC T33(b)) and Code of Practice (CoP (15C).

Validation documentation is in place for containers and packages used for the

transportation of gametes and embryos (SLC T108).

Counselling: (Guidance Note 3)
Independent counselling is offered to all patients and their partners before they provide consent for treatment (SLC T60). Counselling is available throughout the treatment process and following its conclusion, if required. Counselling is also offered to those providing consent to donation, and legal parenthood where donor gametes are used. Where treatment with a surrogate is proposed, alongside the commissioning couple, the surrogate and her partner, where she has one, are counselled as to the implications of such an arrangement.

Counselling services are provided by three counsellors who each work at the centre on a part time basis. Quality indicators have been established and are monitored to assess performance and user satisfaction with the counselling service (SLC T35). A recent audit of counselling services at the centre (SLC T36) highlighted an excessive wait for counselling appointments. This was also expressed as an issue in patient satisfaction surveys. Corrective action was documented and implemented and counselling availability has been increased by 50%. The counsellors also try to offer appointments at more flexible times. The lead counsellor stated that a repeat audit is planned within the year to assess the efficacy of the change to the service.

An SOP for counselling is in place (T33b).

Documented evidence of competence in providing counselling was seen on inspection for all three counsellors providing services at the centre. Two of the counsellors have obtained accreditation from the British Infertility Counselling Association (BICA) whilst the third counsellor is reported to be working towards accreditation.

The counsellors can, when required, refer patients for specialist counselling, for example genetic counselling or counselling for oncology patients.

What the centre could do better.

Nothing noted on inspection.

▶

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: (Guidance Note 11)
The centre does not directly recruit egg or sperm donors. They do however provide treatment with the gametes of known donors introduced by patients themselves and have a third party agreement with an organisation that recruits egg donors within the United

Kingdom (UK). All donor screening, social and medical assessment of prospective donors is conducted at the centre. Prospective donors also see a member of the centre's counselling team before they consent to donation.

An SOP was seen to be in place for the selection and recruitment of donors (SLC T33b). Quality indicators have been established and audits are performed (SLC T35 and T36). The results of the most recent audit were seen on inspection.

Donor sperm is purchased from licensed sperm banks in the UK and from abroad. Donor sperm purchased from outside the UK is imported under General Directions 0006, records of which were seen on inspection.

An audit of six donor files performed on the day of the inspection confirmed that donors are screened in accordance with SLC T52 and relevant professional body guidance, and this is performed in a laboratory with CPA accreditation (SLC T53).

Payment for donors: (Guidance Note 13)
No payment is made to donors. Where compensation is sought by egg donors, the organisation which introduced the donor makes that payment. The centre's third party agreement with this organisation was reviewed on inspection and was seen to state that all donor compensations paid must be compliant with Directions 0001 and that all records of donor payments are readily available to the centre on request. Centre staff reported that where known donors are introduced by patients themselves, compensation is not sought by the donors.

Donor assisted conception: (Guidance Note 20)
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 best parents may do this (SLC T63 (a,and b)).

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

What the centre could do better.

Nothing noted on inspection.

► **Good clinical practice**

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

What the centre does well.

The quality management system: (Guidance Note 23)
There is a comprehensive quality management system in place which includes a quality manual and training and reference materials (SLC T33).

From discussions with staff, observation and a review of documentation at inspection, the inspection team conclude that there are SOPs in place (SLC T33 (b)) to direct all activities to be provided in the course of providing treatment services and, where relevant, they specify any critical materials and reagents used in the procedure described (SLC T31). Quality indicators have been established for the centre's activities (SLC T35) and audits have been conducted within the last two years for the centre's key activities. A sample of audits were reviewed in the course of the inspection (SLC T36). The inspection team considers that the scope and methodology for audit practiced at the centre is well planned and comprehensive and demonstrates that audit is considered an important tool for continuous improvement by centre staff.

Evidence was provided to demonstrate that there are measures in place for reviewing the centre's overall performance, user satisfaction and efficacy of the quality management system to ensure continuous and systematic improvement.

Traceability: (Guidance Note 19)
Centre staff were able to demonstrate that gametes and embryos and materials coming into contact with gametes or embryos used in treatment which may affect their quality and safety are traceable throughout from procurement to treatment or disposal and that there is an SOP to direct this process (SLC T22, T33 (b) and T99).

With the exception of egg collection (see Witnessing section above) dishes are labelled with patient / donor name and a unique identifier (electronic or manual). This was confirmed during the inspection by the observation of three separate witnessing procedures in the laboratory which demonstrated the identification and labelling of dishes containing patient gametes (SLC T101).

Quality indicators relevant to traceability have been established and procedures audited. Several audits were seen by the scientific inspector and included findings, corrective actions and record of their implementation. Staff competence to perform traceability procedures has been documented (SLC T35, T36, T15(a)).

Provision is in place to ensure that the data necessary to ensure continued traceability is stored securely for at least 30 years (and such longer period as may be specified in Directions) (SLC T103).

Process validation: (Guidance Note 15)
Critical procurement and processing procedures have been validated. Documentary evidence of this was seen on inspection (SLC T24 and T72).

Equipment and materials: (Guidance Note 26)
Documented evidence was available to see on inspection which demonstrated all critical equipment (including that for a new embryoscope) used in patient treatment or the storage of gametes and embryos has been validated and will not render the gametes or embryos clinically ineffective or harmful to the recipient (SLC T24 and T25).

Manuals and documented procedures (SOPs) for the operation of all critical equipment

were seen to be readily available to staff in the work areas which included the actions to be taken in the event of equipment malfunction or failure (SLC T27). Key equipment or materials that affect the critical processing or storage parameters where observed to be calibrated to traceable standards and subject to appropriate monitoring and alarms (SLC T24). Documented evidence of regular cleaning, decontamination and preventative maintenance and servicing was also seen (SLC T26 and 28). Sterile instruments are used for the procurement of gametes and embryos. CE marked instruments/materials are used where possible (SLC T30).

Premises and facilities: (Guidance Note 25)
A tour of the centre confirmed that the premises are suitable for the licensed activities and that all activities to which the centre's licence applies are conducted in the licensed premises (SLC T1). Evidence was provided that the processing of gametes takes place in an environment of the appropriate air quality (SLC T20), and that air quality is regularly monitored.

Adverse incidents: (Guidance Note 27)
There is an SOP in place to direct the reporting of adverse incidents or near miss events to the HFEA. Staff were able to describe the process to be followed for reporting and the investigation of an incident or untoward event and demonstrated a good understanding of the nature of events or incidents that should be reported to the HFEA (SLC T118). Adverse incidents reported to the HFEA since the last inspection were reported within the required timescales (SLC T120, T121 and General Direction 0011).

Third party agreements: (Guidance Note 24)
The centre has established written agreements with all third parties who provide goods or services that influence the quality and safety of gametes (SLC T111). Evidence was seen that confirmed that the centre has evaluated the ability of third parties to meet the required standards (SLC T112) and that the content of the agreements is compliant with SLC T113 and T114. A list of all third party agreements in place is maintained by the centre (T103). The inspection team audited four of the centre's third party agreements and considered them to be compliant with standard licence conditions.

ICSI: (Guidance Note 21)
There is a prescriptive SOP in place to direct ICSI practice (SLC T33(b)) which has been validated based on professional body guidelines and published studies (SLC T72). All staff conducting ICSI procedures were able to provided documented evidence of the assessment of the competence in this procedure (SLC T15(a)). Quality indicators for performance have been established and are monitored (SLC T35 and T36). The results of the most recent audit was seen on inspection.

What the centre could do better.

Nothing noted on inspection.

▶ **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 19%.

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than the target at a statistically significant level, unlikely to be due to random variation.

What the centre does well

Ongoing monitoring of the centres 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:

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

The inspection team had the opportunity to review the summary log of women receiving double and triple embryo transfers who meet the criteria for single embryo transfer. Three sets of records were reviewed and all three documented clearly the explanation as to why more than one embryo was transferred and that the risks of multiple pregnancy had been fully discussed with the patient.

What the centre could better.

Nothing noted on inspection

► **Staff engaged in licensed activity**
- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible: (Guidance Note 1)
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 more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. He has held the position of PR at the centre since 2004.

The PR has successfully completed the HFEA Person Responsible Entry Programme Certificate no: T/1059/7.

Staff: (Guidance Note 2)
The centre has suitably qualified staff to carry out all of the licensed activities and associated services provided. All staff, where appropriate, are registered with the relevant professional and/or statutory bodies (SLC T14).

The centre has a stable workforce with a low turnover of staff. The PR confirmed that at this time they have an adequate number of staff to assure patient safety and quality of care (SLC T12). They have recently recruited new members to the team. One of the most recently appointed members of the nursing team was interviewed on inspection and described a comprehensive induction programme (SLC T15).

Evidence was provided that staff are competent in their designated tasks. Samples of staff competence assessments were reviewed and included donor recruitment and assessment, provision of information and obtaining consent (SLCT15(a)).

Laboratory staff competence assessments were seen on inspection as referenced previously in the report.

The PR informed the inspection team that opportunities for professional development are well supported by the Trust. Evidence was reviewed demonstrating that centre staff are given the opportunity to participate in continuing professional development, including attendance at workshops and conferences.

What the centre could do better.

Nothing noted on inspection.

► **Welfare of the Child** (Guidance Note 8)

What the centre does well.

Documented evidence was available to show that patients are not provided with treatment until account has been taken of the welfare of any child who may be born as a result and of any other child who may be affected by the birth (SLC T56).

An audit of five patient records showed that both patient and partner had completed welfare of the child assessment questionnaires and that the forms had been reviewed by a member of the nursing team prior to treatment. A 'matched' file for both a surrogate and the commissioning couple were also noted to have appropriate welfare of the child assessments documented. Staff described that any indication of further information being required to inform the assessment would be documented and concerns discussed within the multidisciplinary team. There is an SOP in place to guide the assessment process (SLC T33(b)).

The centre has audited their welfare of the child (WoC) procedures (SLC T36) and a copy of the audit performed in October 2011 was seen on inspection.

Assessment of staff competencies in WoC assessment were documented and staff interviewed were able to demonstrate a full understanding of WoC requirements (SLC T15(a)).

What the centre could do better.

Nothing noted on inspection

► Embryo Testing

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

What the centre does well.

The centre provides an extensive pre-implantation genetic diagnosis (PGD) service and is also the primary centre for a satellite agreement with The Leeds Centre for Reproductive Medicine (centre 0314) and Jessop Fertility (centre 0196) , for patients who require PGD. All consents to PGD are taken at the primary centre.

The laboratories conducting the embryo biopsy analysis form an integral part of the centre and have CPA (UK) Ltd accreditation.

There is an SOP to direct embryo testing procedures (SLC T33) which has been validated against professional body guidance and published studies (SLC T72). Staff performing embryo biopsy procedures were able to provide evidence of training and the assessment of their competence to conduct this procedure (SLC T15(a and b)). Quality indicators relevant to embryo testing procedures have been established (SLC T35) and the results are regularly audited (SLC T36).

The laboratory manager provided assurance that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressed authorised by the HFEA (SLC T88 (a))
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons (SLC T88(b))
- embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority (SLC T89)
- biopsied embryos are not transferred into a woman in the same cycle of treatment as non-biopsied embryos (CoP 10.4)

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

What the centre could do better.

Nothing noted on inspection.

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: (Guidance Note 29)
From the information provided, observations made and discussion with staff, the inspection team were assured that all licensed activities are conducted in a non-discriminatory manner with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients and their partners and that information is kept confidential and only disclosed in circumstances permitted by law (SLC T43).

Confidentiality and privacy: (Guidance Note 30)
A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43 and T44). Access to the centre is restricted and key pad locks provide additional restriction to sensitive areas. A tour of the centre confirmed that patient records are stored securely.

SOPs are in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (T33 (b)). Evidence of training in confidentiality for the administration team was seen on inspection.

Complaints: (Guidance Note 28)
The centre actively seeks patient feedback and investigates and learns from patient complaints.

The centre's complaints log for the period January 2012 - December 2012 was seen on inspection. The log included the nature of the complaint and the action taken to resolve it.

Costed treatment plans: Guidance Note 4
Before treatment, storage or both are offered, a personalised costed treatment plan is

provided to the patient and her partner (where applicable) and the proposed plan is discussed prior to treatment commencing. A copy of the costed treatment plan provided was seen in medical records reviewed where treatment was self funded (CoP 4.3),

Egg sharing arrangements: (Guidance Note 12)
The centre does not currently facilitate egg sharing.

Surrogacy: (Guidance note 14)
The centre has a surrogacy programme and the patient records of a commissioning couple and host were reviewed on inspection. All parties were seen to have been offered counselling and all consents were in place. The commissioning couple had been screened and registered as donors (SLC T52 and 53).

What the centre could do better.

Nothing noted on inspection

► **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.

Information :
From discussions with staff, documents reviewed and feedback given by patients in questionnaires submitted to the HFEA, the inspection team conclude that detailed information about the nature of the treatment, consequences and risks, tests, confidentiality, consent, and the availability of counselling is given to patients consenting to treatment or to donation or to donation to research. Those giving consent are given adequate opportunity to discuss the implications of their consent before treatment or donation commences. The centre submitted a suite of patient information prior to the inspection. The information submitted was audited by the inspection team and was considered to meet the recommendations of the CoP. Centre staff confirmed that the specific information not provided in leaflets is provided verbally during appointments, prior to obtaining consent.

All prospective patients are invited to attend an information evening which is held monthly at the centre. Topics discussed include a description of treatments offered and the risks of multiple pregnancy.

The centre's website was reviewed by the lead inspector and was considered to be compliant with the HFEA Chairs letter Ch(11)02.

SOPs for provision of information were seen to be in place in addition to quality indicators and audits (SLC T33(b), T35 and T36). A recent audit of the provision of information was seen by the lead inspector and included observation of an information giving appointment and adherence to the SOP and check list. One non-conformity was noted and this was discussed at a team meeting: changes were made to the relevant SOP and all staff were made aware of the changes.

The centre provides treatment with donor gametes to women and couples who may or may not be married or in a civil partnership. Those affected by legal parenthood legislation are informed of how the nomination of a second legal parent affects them and of the consent process prior to treatment being offered (SLC T60).

What the centre could do better.

Nothing noted on inspection.

► **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)
Centre staff provided evidence that written consent is obtained from patients prior to treatment and the centre has a documented SOP for obtaining consent (SLC T33 (b)).

Quality indicators have been established and audits performed (SLC T35 andT36). An audit seen by the inspection team documented that no non conformities were observed.

Centre staff explained that photographic evidence is used to verify patient/partner identity in addition to a check of a signature against the original in the patients file. Evidence of this was seen in the files reviewed on inspection (CoP 5.10).

Consent to legal parenthood: (Guidance Note 6)
SOPs were seen to be in place to guide the process for obtaining the relevant written records of consent to parenthood (SLC T33(b)). Staff interviewed on inspection confirmed that information regarding legal parenthood is given. Staff demonstrated an understanding of the process for consenting and the need to ensure that should a nominated second parent withdraw their consent the woman would not be treated until she had been informed (SLC T64(b)).

What the centre could do better.

Nothing noted on inspection.

3. Protection of gametes and embryos

Focus

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

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

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

What the centre does well.

Discussions with the PR and Quality Manager and a tour of the centre demonstrated that the activities authorised by the centre's licence are carried out at the premises specified in the licence (SLC T1).

The inspection team considered that staff at the centre have respect for the special status of the embryo when carrying out assisted conception treatment services.

The centre does not directly recruit donors and therefore does not provide compensation. The donors treated at the centre are either known donors who do not receive compensation or donors recruited by an agency who have responsibility for the compensation aspects of the donation.

What the centre could do better.

Nothing noted on inspection.

► **Storage of gametes and embryos**

- Storage of gametes and embryos (Guidance Note 17

What the centre does well.

An SOP is in place for the procedure for storing gametes and embryos (SLCT33(b)). Procedures have been validated and quality indicators established (SLC T72, T75 and T35).

Audits have been performed and the results of an audit performed in 2011 were available on inspection (SLC T36).

Staff competence is assessed and practice audited against the centre's SOP (SLC T15(a) and T36).

The laboratory manager confirmed that prior to storing their gametes and embryos patients are screened in accordance with SLC T50 and T51. This was confirmed in SOPs, checklists and in patient records seen on inspection.

The centre operates a 'bring forward' system to ensure gamete providers have sufficient notice of the end of their consented storage period, the SOP for which was seen on inspection.

What the centre could do better.

It was noted on inspection that embryos belonging to one patient and sperm belonging to another patient were in store beyond the consented period. Both patients had indicated in writing that they wanted to continue storage but had not as yet completed consent forms to that effect. It was also noted that the expiry date of consent was the day prior to the inspection.

► **Distribution and / or receipt of gametes and embryos**

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

What the centre does well.

An SOP was seen to be in place detailing the circumstances, responsibilities and procedures for the release of stored material before distribution (SLC T33b). SOPs include a recall procedure and procedures for the handling of returned gametes and embryos.

The centre team were able to provide evidence that they had complied with all the requirements of Directions 0006 when importing or exporting gametes or embryos.
The scientific inspector reviewed the details of two imports received by the centre and confirmed that in these instances the requirements of Directions 0006 had been met.

What the centre could do better.

Nothing noted on inspection.

► **Use of embryos for training staff** (Guidance Note 22)

What the centre does well.

The centre staff described a process whereby embryos used for training are stored separately from those used in treatment (SLC T92). Embryos are only used for training activities authorised by the Authority (SLC T93).This was evidenced on inspection by reviewing the training log.

Patients' consent to use of their embryos in training is documented and checked at the time of embryo culture. The centre's SOP was seen to include procedures to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of training (SLC T95).

Patient information on the nature of training for which the embryos will be used is provided verbally and in writing. Written information provided was reviewed on inspection and considered to be appropriate (SLC T97).

What the centre could do better.

Nothing noted on inspection

4. Good governance and record keeping

Focus

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

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

▶ **Record keeping** • Record keeping and document control (Guidance Note 31)
What the centre does well. All patient records reviewed during the inspection were seen to be clear and legible and satisfied all of the requirements of SLC T46. Each record reviewed included: patient/donor first name, surname, date of birth, age and sex, details of how the patient/donor had been identified (passport/driving licence), the treatment provided, a medical history, welfare of the child assessment, relevant documented consents and clinical and laboratory data and the results of tests carried out. Procedures are in place to ensure records are protected from unauthorised amendment, are retained and can be retrieved throughout the designated retention period (SLC T47). Documents submitted to the HFEA as part of the renewal application and viewed on inspection were seen to be controlled, recording the history of document reviews and systems are in place to ensure that only the current version is in use and accessible to staff (SLC T34).
What the centre could do better. Nothing noted on inspection

▶ **Legal requirements** [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32) • Licensed treatment reporting
What the centre does well. The PR provided all information required by the application process prior to inspection. Centre staff cooperated with the inspection team and further information requested was provided in a timely manner. The centre has a SOP describing the processes by which treatment data is entered by the centre on the HFEA register (SLC T33b) and relevant quality indicators for register data entry are monitored (SLC T35).

To assess the timeliness of submission of information to the HFEA register, the reporting of 172 recent treatments (119 IVF and 53 DI treatments) on the centre's treatment database was reviewed against the HFEA register. This audit found that all but one IVF treatment and all DI treatments were on the HFEA register at the time of the inspection. A single recent cancelled IVF cycle had not been reported to the register and this omission was immediately corrected by the centre staff. The inspection team considered that the centre's normal reconciliation processes would have identified this treatment cycle and reported it to the HFEA. Regarding the timeliness of data entry, 80% of IVF and 69% of DI treatments within the audit sample were submitted to the HFEA within the period required by General Direction 0005.

To ascertain the accuracy of register data submission, the content of 53 recent assorted data forms on the register were reviewed against source documentation in patient and donor medical records. No errors or omissions were found in the register data which would prevent the authority fulfilling its statutory obligations, nevertheless, issues were found with the provision of donor information, as discussed below.

What the centre could do better.

The register submission accuracy audit found two instances of donors and patients being registered with the same number. The audit sample was too small to conclude whether these are systematic errors or isolated occurrences however it is possible that other donors and patients may be affected. The audit sample also included four instances where a donor's personal information/goodwill message/pen portrait, available in the medical records, had not been submitted to the HFEA. A list has been provided to the centre that includes a number of other donors where this may also be the case and where the use of the donor's gametes has resulted in pregnancies and live births. These errors in donor data submission are non-compliant with General Direction 0005. The designated HFEA Form Returnee has been provided with the relevant patient numbers, form numbers and error details so that necessary corrections can be made.

Given the errors in donor data submission to the register discussed above, it is notable that the SOP describing the processes by which data is entered on the HFEA register does not clearly define who is responsible for performing specific tasks, including the submission of donor information to the register (SLC T33b). The centre staff were also unsure regarding the regulatory requirements regarding the submission of donor information and who was responsible for it, suggesting training in this area is deficient (SLC T15).

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.

A tour of the centre confirmed that access to all confidential information is restricted to authorised personnel (SLC T43). Access to the centre is restricted and key pad locks provide additional security in sensitive areas. Patient records were seen to be stored

securely.

The centre ensures that information about people having treatment, donors and children born as a result of assisted conception is not disclosed unless the relevant consents to do so have been provided.

The centre seeks consent from patients to the disclosure of their identifying information, held on the HFEA register, to medical or other researchers. The inspection team audited 19 forms in the medical records recording consent to disclosure to researchers, against the consenting decision submitted by the centre to the HFEA register. Of the 19 forms, 13 were completed appropriately and the consenting decisions concurred with those held on the HFEA register.

What the centre could do better.

In four (21%) of the 19 disclosure consent forms audited, discrepancies were noted between the consenting decision recorded in the medical records and that recorded on the HFEA register. In each instance consent had been given but the register recorded that it had been withheld. Thus the centre's data submission to the HFEA has been inaccurate (SLC T9e). In a further two forms (11%), the section of the disclosure consent form covering the use of identifying register information for research purposes had not been completed. In both instances, the register records that consent had been withheld. This may be an inaccurate interpretation; additionally it may reduce the pool of data available to researchers.

5. Changes / improvements since the previous inspection on 20-21 March 2011

Area for improvement	Action required	Action taken as evidenced during this inspection
In 2011 the centre took an average of 30 days to pay invoices which is in excess of the timescale set out in CH(10) 02 (SLCT9d).	The PR should ensure that invoices are paid within the required timescales.	The HFEA finance department report that invoices are now paid within the required timescales. 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
None			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
At the time of inspection the submission of some donor information for a number of donors was outstanding (General Direction 0005). There was uncertainty amongst the staff about the requirement to provide this information to the HFEA and also who was responsible for providing it, suggestion a training need (SLC T12). The SOP documenting the processes for register data submission also does not define who is responsible for reporting donor information to the register (SLC T33b).	The PR should ensure that donor information, notably pages 3 & 4 of the donor registration form, is provided to the Authority in accordance with General Direction 0005. The PR should review the SOP documenting the processes by which data is submitted to the HFEA and ensure that the responsibilities for data submission are clearly defined, notably in relation to the provision of donor information to the register. The PR should ensure that staff involved in data submission processes are adequately trained and provided with sufficient on-going training and support to	This omission has been recognised and rectified. Measures have been put in place to avoid reoccurrence (refresher training of the relevant staff, SOP reviewed and recirculated to relevant staff). The opportunity was taken to discuss this at the team meeting to ensure that all members of the team are clear as to this requirement. The overarching SOP was supplied before the HFEA Inspection as requested. SOPs which detail the specific tasks and responsibilities for EDI data submission of staff are in place,	No further action.

	enable them to effectively discharge their duties. The PR should provide the lead inspector with the updated SOP and evidence of staff training by 16 April 2013.	available and supplied with this response. EDI responsibilities are clearly defined and assigned to individual members of the team. All managers and staff involved in EDI data submission are known to each other. New members of staff are trained and signed off as and when competent. We use the HFEA guidance documents on how to complete EDI forms and the HFEA EDI User Guide during the training process. On several occasions a member of the HFEA registry team has come to the ACU to train staff. Prior to the inspection several members of the team were being trained to undertake EDI data submission. During the training period it is inevitable errors will be made. Also from time to time errors will occur. The completed training forms for the two members of staff are provided with this response. The EDI errors are identified and resolved whenever they occur or from our monthly EDI	

		data audits. These audits also identify individuals who require additional training which is provided as required and appropriate.	

► 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 register submission accuracy audit found two instances of donors and patients being registered with the same number.	The PR should ensure that different individuals are registered with the HFEA with unique patient/donor numbers. An audit should be conducted to identify whether other individual patients and donors have been registered with the HFEA with the same patient/donor numbers. This audit should be submitted to the HFEA by 16 April 2013. Any corrective actions necessary should be implemented by 16 July 2013.	When importing donor gametes or embryos from another centre we have been required by the HFEA to use the donor code provided by the originating centre to ensure the 10 family limit can be tracked. By chance a number of the imported donors registered with the HFEA have had a numeric code identical to a local patient code. This was discovered post inspection, discussed with the HFEA Registry Team and a solution found prior to receiving the draft inspection report. The requested audit was completed on the 21 February 2013 and is provided with this response. The corrective action was completed on 6 March 2013.	No further action.
At the time of inspection, the centre had embryos for one	The PR must ensure that the bring forwards system is effective in	The non-compliance was the result of the two patients, who	No further action.

patient and sperm for a second patient in store beyond the consented storage period. Both patients had indicated in writing that they wanted to continue storage but had not as yet completed consent forms to that effect. Guidance issued by the HFEA in Chair's letter CH(03)03 indicates that where there may be legal challenge to the disposal of gametes or embryos (as might reasonably have been the case as the gamete providers in this case had indicated an intention to extend consent to storage) embryos should not be disposed of. For this reason this non-compliance has been classified as "other". . HF&E Act, as amended, Sch 3 para 8 (1) .	providing adequate opportunity for patients to extend consent before the expiry of existing consent The PR should review the centre's bring-forward system, the staffing resources available to manage it, the disposal arrangements at the expiry of storage consent and the written information provided to patients regarding storage consent. The PR should provide the lead inspector with a report of the review of the bring-forward system and evidence of staff training in the new system by 16 April 2013	had indicated in writing that they wished to extend the storage of stored material, not completing and returning the relevant consent form to the centre in the required time frame. The patients were initially contacted a year before the expiry date of the material and numerous times during that period; until a response was obtained. The patients were provided with the relevant consent form and patient information. The non-compliance is not related to the bring forward system, staffing, disposal arrangements etc; which had all been followed. These do not need to be reviewed as they have not contributed or caused the non-compliance. The non-compliance is solely due to the two patients choosing not to complete and return the relevant consent forms within the given time frame even though the centre had done everything reasonably within its'	

		powers starting a year before the expiry date of the material. It is important to note that expiry of the storage period only occurred 48 hours before inspection and was resolved shortly afterwards as communicated with the inspection team.	
The tubes used during egg collection are not marked with patient identifiers (SLC T101).	The PR should either ensure that the tubes are appropriately labelled during egg collection, or should ensure the practice is risk assessed. The PR should provide the inspector with a documented risk assessment including any corrective actions and the timescale for their implementation if relevant by 16 April 2013.	Please refer to the HFEA Inspection Report dated July 31st 2009 and the associated Minutes dated December 14th 2009 in which the HFEA accepted the current practice; which has not changed since. At that time we provided the relevant risk assessment which was completed in August 2009 and can be found on TRIM. However an updated risk assessment is provided.	No further action.
Discrepancies were identified between the consent recorded on the patient and partner disclosure consent forms found in patient files and the disclosure consent decision submitted by the centre to the HFEA register (SLC T9e and Chair's Letter CH(10)05)	The PR should review procedures for checking and submitting consent to disclosure decisions to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective	The procedure A-GEN-P0020 which covers submitting patients' choices regarding research consent on the HFEA Consent to Disclosure (CD) Form to the HFEA via EDI has been reviewed and subsequently audited. A copy of the audit is provided	No further action.

	actions should be submitted to the HFEA by 16 April 2013. Three months after the implementation of corrective actions the centre should audit a random sample of ten patient records to ensure that the consent to disclosure to researchers taken from patients has been correctly submitted by the centre to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA by 16 July 2013. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application by researchers is made for the release of that information.	with this response. As a corrective action additional training has been provided for the staff responsible for submitting EDI registration forms regarding the interpretation of the research consent choices. This was completed on the 6 March 2013. Additionally preventative action is to audit EDI registration form data integrity on a monthly basis and correct any errors found. When no transcription errors are seen for several months the time frame between audits will be increased.	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

26 April 2013

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

Minutes – Item 2

Centre 0102 – (Guys Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Hannah Darby – Senior Policy Manager David Moysen – Head of IT	Rebecca Loveys

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

The Panel also had before it:

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

Consideration of Application

1. The Panel noted that this is a very large centre which provides treatment (including embryo testing) and storage, which has been licensed by the HFEA since 1992.

2. The Panel noted that HFEA data for October 2011 to September 2012 show the centre's success rates for IVF/ICSI are in line with the national averages.

3. The Panel noted that the centre reported 97 cycles of partner insemination for 2011 with 13 pregnancies. This equates to a 13% pregnancy rate which is consistent with the national average.

4. The Panel noted that, at the time of inspection, one major and four other areas of non-compliance were identified by the Inspectorate.

5. The Panel noted that, commendably, since the inspection, all these areas of non-compliance have been addressed.

6. The Panel noted that the multiple birth rate for 2010/11 is likely to be better than the target. Also, the rate for 2011/12 is not likely to exceed the target .

7. The Panel commended the centre on its efforts with minimising multiple births.

8. The Panel noted that the centre uses embryos for training and that there were no non-compliances reported for this activity.

9. The Panel noted the discourse relating to donor information, as described on page 79 of the inspection report.

10. The Panel noted the subsequent improvement the centre has made on consent for research and that it has addressed the SOP issue and list of errors as set out on page 79.

Decision

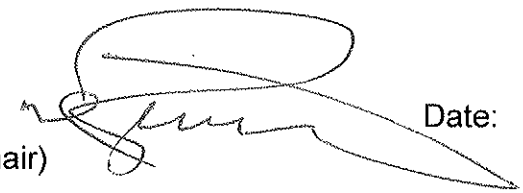
11. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

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 agreed with the Inspectorate's recommendations made in the report and noted they had since been addressed. The Panel agreed to renew the centre's Treatment (including embryo testing) and Storage licence for a period of four years with no additional conditions.

Signed:  Date: 7 May 2013

Mark Bennett (Chair)