Inspection Report

Purpose of the Inspection Report
This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 23 and 24 April 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'

Inspection details:
The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Date of Executive Licensing Panel: 05 July 2013

Centre details

Centre name	Assisted Conception Unit, King's College Hospital.
Centre number	0109
Licence number	L/0109/12/f
Centre address	Kings College Hospital, Denmark Hill, London. SE5 9RS.
Person Responsible	Dr Mike Savvas
Licence Holder	Mr Peter Fry
Date licence issued	01 October 2008
Licence expiry date	30 September 2013
Additional conditions applied to this licence	None

Contents

Section 1 : Summary Report

Brief description of the centre and its licensing history:
The Assisted Conception Unit at King's College Hospital has held a licence with the HFEA since July 1992.

The centre provides a full range of fertility services, and has one transport centre Epsom and St Helier NHS Trust centre 0259).

The centre provided 602 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2013. In relation to activity levels this is a medium sized centre.

In June 2012 an ELP approved a variation to the centre's licence allowing the relocation of the centre to new licensed premises. The new unit is a self-contained facility, within the grounds of King's College Hospital.

The centre has recently appointed a new Licence Holder, Mr Peter Fry; a variation to the role was agreed at the ELP meeting on 23 May 2013.**Activities of the centre:**

Type of treatment	Number of treatment cycles for 01 Mar 2012 - 28 Feb 2013
In vitro fertilisation (IVF)	247
Intracytoplasmic sperm injection (ICSI)	264
Frozen embryo transfer (FET)	48
Donor insemination (DI)	43
Partner insemination (01 January 2012 – 31 December2012)	30

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

Outcomes*

For IVF and ICSI, HFEA held register data for the period January 2012 to December 2012 show the centre's success rates are in line with national averages.

In 2012 the centre reported 30 cycles of partner insemination with two pregnancies, which is consistent with the national average.

Between 1 April 2010 and 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represented performance that was not likely to be statistically different than the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 20%: this represented performance that was not likely to be statistically different from the 15% multiple live birth rate target for this period.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

Summary for licensing decision – pre review of draft by PR

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the PR is suitable and 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 4 major and 10 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented;

Major areas of non compliance:

- The PR should ensure that there is a written agreement with the transport centre.

Other areas of practice that require improvement:

- The PR should ensure that the local induction policy is used in the laboratory for staff new to the centre.

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

Major areas of non compliance:

- The PR should ensure that critical procurement and processing procedures have been validated.
- The PR should ensure that all critical equipment is validated and serviced at the frequency specified by the centre, and the cleaning log for equipment should be completed after each clean.
- The PR should ensure that no gametes are kept in storage for longer that the consented period.

"Other" areas of practice that require improvement:

- The PR should ensure that laboratory staff record the identification of samples at all critical points of the clinical and laboratory process.
- The PR should ensure the witnessing procedure includes an extra step during embryo freeze.
- The PR should ensure that the tubes are appropriately labelled during egg collection.

- The PR should ensure that the background air quality in areas where the processing of gametes and embryos takes place is at least grade D quality.
- The PR should ensure that prior to giving consent, each gamete provider is provided with the necessary patient information.
- The PR should ensure that the centre's website meets the requirements of Chair's Letter CH (11)02.
- The PR should ensure that there is a written Standard Operating Procedure (SOP) available for laboratory staff for;
  - Ø Use of embryos in training.
  - Ø Responding to equipment failure or malfunction.

  The witness SOP should include;
  - Ø Disposal of embryos.
  - Ø Egg freezing and thawing.

  The background air quality SOP should include;
  - Ø Air quality particle counting.
- The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA.
- The PR should review the timescales for reporting donor insemination cycles to the HFEA.

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

The inspection team is satisfied that activities carried out at the centre are necessary or desirable to provide licensed treatment services.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of 4 years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

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

What the centre does well.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

At the inspection, 10 sets of witnessing records from within the patients' notes were reviewed. The witnessing signature of one staff member was missing in two patients' notes; this was discussed with staff at the centre, who confirmed it was an omission of the staff documenting the witnessing step (SLC T71). Recommendation 5.

Staff do not witness one step during the embryo freeze stage: cross checking the identifiers on the label of the storage container against the label on the freeze dish at the time of transfer. Staff do indirectly complete this step, but, by performing this as a separate witnessing step, it would minimise risk even further (SLC T71). Recommendation 6.

The witnessing SOP does not include witnessing during egg freezing, egg thawing or at the disposal of embryos. Staff are performing these steps, but they are not documented in the witnessing SOP (SLC T33b). Recommendation 12.

Patient selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and donors
The centre's procedures for screening patients and donors are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors
Payments to donors are fully in line with the requirements of the HFEA. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully in line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Nothing noted at the time of this inspection.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The centre is being proactive in adapting their strategy to meet the HFEA's multiple birth rate target.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) to identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (Guidance note 23)
The centre has a quality management system in place that is compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the supply of goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos with one exception which is documented below.centre

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activities are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff, with some exceptions noted below.

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice**.** Diagnostic testing is carried out in a laboratory that is accredited by Clinical Pathology Accreditation (CPA) UK Ltd. Semen analysis is carried out in the centre;s own laboratory which was considered to have accreditation to an equivalent standard.

Adverse incidents (Guidance note 27)
The centre reports adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

Transport centre management (Guidance Note 24)
The centre has audited success rates for transport patients from Epsom and St Helier NHS Trust (centre 0259) and an annual visit takes place to review practice. The transport centre had an HFEA renewal inspection in November 2011 and no non-compliances were cited in the report.

What the centre could do better.

Process validation (Guidance Note 15)
The centre has not completed the validation of all critical processing procedures to ensure that they are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Staff are aware of the requirement and have partially completed validation templates based on a retrospective analysis of the centre's own data and published studies.

(SLC T72). Recommendation 1.

Traceability (Guidance Note 19)
The tubes used during egg collection are not marked with patient identifiers. The tubes are used to transfer eggs within follicular fluid from the theatre to the laboratory; the aspirate is then transferred to dishes marked with the appropriate patient identifiers (SLC T101). Recommendation 7.

Equipment and materials (Guidance Note 26)
A log recording the cleaning of equipment in the laboratory was not being completed for all equipment (SLC T26). Recommendation 2.

All equipment had been serviced in the last year, but not always within the timescale specified by the centre, for example the incubators scheduled by the centre for service every 6 months was due (according to the centres' record) 01 November 2012 but was outstanding at the time of the inspection (SLC T24). Recommendation 2.

The validation documents for one piece of equipment (the dry shipper) had not been completed at the time of the inspection (SLC T24). Recommendation 2.

The centre does not have an SOP in place documenting the action to take in the event of equipment malfunction or failure (SLC T33b). Recommendation 12.

Premises and facilities (Guidance Note 25)
Air quality in the critical work area is monitored via particle counts and is grade A. Background air quality was monitored via settle plates in March 2013. However, the results of the monitoring were not provided in a format from which the grade of air could be interpreted (SLC T20). Recommendation 3.

The centre does not have an SOP for measuring air quality via particle counts (SLC T 33b). Recommendation 12.

Transport centre (Guidance Note 24)
There was no written agreement with the transport centre available for review at the inspection, this document should include a definition of respective responsibilities, and the process by which the transport centre is carrying out the following;

i. The elements of treatment, including monitoring of patients.
ii. Welfare of the child assessments
iii. Counselling
iv. Patient information
v. Completion of consent forms
vi. Submission of HFEA data submission forms

General Directions 0010(9). Code of Practice (CoP)24.4. Recommendation 3.

In an audit of five sets of patient notes, one set of notes did not record the temperature or the identifying number of the transport incubator used to transfer gametes between the transport centre and King's College Hospital.

This is important for the traceability of the equipment and the monitoring of critical parameters to confirm that the temperature of the transport incubator was within an acceptable range. (SLC T24) (CoP guidance18.4 (k). Recommendation 3.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1150/8).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.

At the interim inspection in July 2012, the inspection team were advised by the PR that staffing levels would be compromised in 2012 (in the laboratory) due to maternity leave and the resignation of the Consultant Embryologist. The centre completed a workload review recommended by the inspection team, and were open and transparent about the reduction in workload, and the need to recruit staff. Unfortunately the recruitment process has taken longer than expected, and the impact on the laboratory workload has potentially led to a number of non-compliances noted in the report, for example updating SOPs and validation of processes. This was discussed at the inspection, and the PR said that lessons had been learnt in the process and staff were now keen to address the recommendations made as they now have a full complement of staff.

Staff (Guidance Note 2)
The centre has policies to support induction training, but the local induction templates were not used for the most recently employed member of the laboratory team (SLC T15). Recommendation 10.

Welfare of the Child (Guidance Note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre 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.
What the centre could do better. Nothing noted at the time of this inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further nine patients also provided written feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with five of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better.

Nothing noted at this inspection.

Treating patients fairly

What the centre does well.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements to ensure protects the rights of the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)
The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors.

Counselling (Guidance note 3)
The centre's counselling staff and procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

What the centre could do better.

Nothing noted at the time of this inspection.

Information

What the centre does well.

The centre's procedures for providing information to patients and donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of a costed treatment plans (Guidance note 4)
The centre provides an individual costed treatment plan to all self-funding patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.

Information for gamete providers
The written information for gamete providers did not contain all the HFEA requirements; It was not clear what information will be fed back to the gamete provider (SLC T97). Recommendation 9.

Information on the centre's website
The centre's website is not compliant with Chair's Letter CH (11)02 in the following area:

- The website does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type. Recommendation 11.

Consent

What the centre does well.

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients.

Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of the patient's consent, so that it only releases the patients identifying information, to researchers, with their consent

What the centre could do better.

Disclosure of information, held on the HFEA Register, for use in research
The HFEA audit team reviewed 10 patient and partner consent to disclosure forms against the disclosure consent decisions communicated by the centre to the HFEA register. Discrepancies were found between two completed patient/partner disclosure consents on patient files and the related consent data held on the HFEA register.

In both instances consent to the use of identifying register data for research purposes has been given, but the HFEA register records showed that it had been withheld. Guidance supplementary to Chair's Letter CH (10)05 and General Direction 0007. Recommendation 13.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises, or on the premises of the transport centre.
- 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.

What the centre could do better.

Nothing noted at the time of this inspection

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers, with the exception noted below.

What the centre could do better.

A review of the centre's records of consent to storage of gametes and embryos on inspection showed that sperm samples for one patient were being stored after the expiry of the consented storage period (HF&E Act 1990 (as amended) Schedule 3, 8 (1) and 8 (2)). The inspection team were satisfied that the centre's 'bring forward' system was effective, and that this was not a systemic problem. Staff were made aware via the bring forward

system of the need to seek further consent from the patient and were waiting for consent forms to be returned. HF&E Act, as amended, Schedule 3 paragraph 8 (1). Recommendation 4.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are compliant with HFEA requirements.

This ensures that all gametes or embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

Nothing noted at the time of this inspection.

Use of embryos for training staff (Guidance Note 22)

What the centre does well.

The centre's procedures for using embryos for training staff are broadly compliant with HFEA requirements. This ensures that embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The centre uses embryos to train staff in the following activities:

- Vitrification
- Embryo handling and manipulation

All of these activities have been authorised by the Authority.

What the centre could do better.

The centre's patient information details the nature of the training for which embryos will be used, that the decision to donate will not affect their treatment and that they can vary/withdraw consent until the point of use. However, it does not include details on whether any information will be fed back to them (SLC T97). Recommendation 9.

The centre does not have an SOP for the use of embryos in training, to ensure there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services (SLC T95). Recommendation 12.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are broadly compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

To determine whether all licenced treatment activity is reported to the HFEA within required timescales, a sample of treatments undertaken over a 12 month period recorded within the centre's laboratory records was compared to data submitted by the centre for inclusion on the register.

The centre reports IVF treatment cycles in a timely manner. All of the sample of 115 IVF treatment cycles were on the HFEA register, with 97% being submitted with the five day deadline specified in Directions 0005.

What the centre could do better.

Out of a sample of 40 donor insemination cycles in the audit sample there was one that had not been reported to the register by the inspection date. 72% of donor insemination cycles were reported within the five working days deadline specific in Directions 0005. (General Directions 0005. SLC T9 (e) / T41). Recommendation 14.

Section 3: Monitoring of the centre's performance

Following the interim inspection on 24 July 2012, recommendations for improvement were made in relation to one area of critical non-compliance, two areas of major non -compliance, and two 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented but it is noted that the non-compliance in the last report (relating to storage of cryopreserved gametes for 16 patients after expiry of consent) is the subject of a further recommendation in this report. The inspection team were satisfied however, that the centre's 'bring forward' system is effective and that the recurrence of this non-compliance is not indicative of a systemic problem.

Section 4: Areas of practice that require action

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 noted			

Major area of non compliance

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

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

Area of practice and Reference	Action required and timescale for action	PR Response	Executive Review
1. Process validation The centre does not have documented evidence that critical procurement and processing procedures had been validated (SLC T72).	The PR should ensure that validation is completed and documented for all critical procurement and processing procedures. An action plan stating how validation will be addressed and a timeline for completion should be sent to the centre's inspector by 24 July 2013. A sample of validation documents will be requested for review by the centre's inspector.	The validation action plan and timeline for completion will be submitted by the 24th of July, with validation documents being made available for review as requested.	The inspector will ensure that the agreed date for submission of the validation documents is reviewed on or before 24 July 2013, and action taken accordingly. Further action required.
2. Equipment and materials. a) The centre had not completed the cleaning log to show that the maintenance	a) The PR should ensure that a cleaning log is maintained for all critical equipment.	We have contacted the relevant companies regarding servicing outstanding and will submit confirmation that this	The inspector will ensure that the agreed date for submission of the outstanding document is reviewed on or before 24 July

and cleaning of critical equipment was performed regularly (SLC T26). b)The centre did not have documented evidence of the maintenance and regular inspection of equipment. c) The dry shipper has not been validated, other equipment had all been validated at the time of the inspection (SLC T24).	b) Critical equipment must be maintained and inspected in accordance with the manufacturer's instructions or documented procedure determined by the centre. c) The dry shipper must be validated. Corrective action should be taken and the PR should provide assurance to the centre's inspector that cleaning log is now being completed, and that equipment is maintained and inspected. The PR should inform the centre's inspector when the dry shipper has been validated, on or before 24 July 2013.	has been carried out as requested. Validation of the dry shipper is in progress Corrective action and confirmation of completion of the steps above will be submitted by the 24th of July	2013, and action taken accordingly. Further action required.
3. Transport centre. There was no written agreement with the transport centre available for review at the inspection, this should include a definition of respective responsibilities, and the process by which the transport centre is carrying out the following;	The PR should ensure that the written agreement is submitted to the centre's inspector for review by 24 October 2013. The temperature and identification number of the transport incubator should be recorded in the patient records.	A Third Party Agreement and Transport SOP are in place with St Heliers which contain details as required by General Directions 0010 (9). A copy of the SOP was provided at the time of the inspection along with the TPA. Further copies of the documents in place at the time of the inspection and the	The inspector is satisfied with the information submitted with the report. No further action.

i. The elements of treatment, including monitoring of patients. ii. Welfare of the child assessments iii. Counselling iv. Patient information v. Completion of consent forms vi. Submission of HFEA data submission forms General Directions 0010(9) The transport incubator temperature and identification number was not recorded in one set of patient records (CoP18.4 (k).(SLC T24).	The PR should audit the patient records to ensure staff record the temperature and identification number of the transport incubator. A summary report and corrective action should be sent to the centre's inspector by 24 October 2013.	updated TPA and draft of reviewed are attached to this report. In April 2013 just prior to the inspection a retrospective audit of traceability information, witnessing and the documentation of incubator number and temperature was carried out on 19 sets of records belonging to transport patients who had egg collections between December 2012 and February 2013 . The audit identified that on two occasions incubator number was not documented and on one occasion incubator temperature was not documented. This was fed back to the team at St Heliers along with the Corrective Action notice. Copies of the audit summary and Corrective Action Notice will be forwarded with this report. An early re-audit is scheduled for July 2013.	
4. Consent to storage The centre had sperm samples from one patient in storage	The PR must ensure that consent is received as a matter of urgency.	Telephone contact has been made with the patient and we have received verbal consent	The inspector will ensure that the agreed date for submission of the outstanding confirmation is

after the expiry of the consented storage period. HF&E Act, as amended, Schedule 3 paragraph 8 (1)	Once a decision has been made the PR is asked to inform the centre's inspector immediately, or before 24 July 2013 at the latest.	to dispose of the samples. We are awaiting the receipt of the signed paperwork to confirm this decision. We will submit confirmation of the final decision and actions as requested.	reviewed on or before 24 July 2013, and action taken accordingly. Further action required.

Other areas of non-compliance or poor practice

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
5. Witnessing audit An audit of the witnessing records in patients' notes showed that two out of 10 records had no witnessing signature by a second member of staff (SLC T 71).	The PR should ensure that the witnessing checks are recorded at the time the relevant process/ procedure takes place. An audit of witnessing documentation was last completed in October 2012. It is recommended that an audit is repeated by October 2013. A copy of the summary report should be sent to the centre's inspector by 24 January 2014.	The team have been reminded of the need to sign for witnessing checks at the time the process/ procedure takes place. As requested a copy of the audit summary report will be forwarded by the 24th of January 2014.	The inspector will ensure that the agreed date for submission of the outstanding audit summary is reviewed on or before 24 January 2014, and action taken accordingly. Further action required.
6. Witnessing Staff do not specifically witness one step during embryo freezing	The PR should ensure the witnessing procedure includes this additional step during	A copy of the witnessing SOP and associated paperwork will be submitted by the 24th of	The inspector will ensure that the agreed date for submission of the outstanding audit

as recommended by HFEA guidance on witnessing; checking identifiers on the label during the transfer of gametes between the freeze dish and the straw (SLC T71).	embryo freeze. A copy of the updated witnessing procedure to reflect the change of practice, should be sent to the centre's inspector by 24 July 2013.	July as requested.	summary is reviewed on or before 24 July 2013, and action taken accordingly. Further action required
7. Labelling containers The tubes used during egg collection are not marked with patient identifiers. The tubes are used to transfer eggs within follicular fluid from the theatre to the laboratory; the aspirate is then transferred to dishes marked with the appropriate patient identifiers (SLC T101).	The PR should either ensure that the test tube at egg collection is appropriately labelled during egg collection, or should ensure the practice is risk assessed. A copy of the risk assessment and any corrective action should be sent to the centre's inspector by 24 July 2013.	We are currently undertaking a risk assessment prior to making a decision about how to proceed with this. A copy of the risk assessment/ updated SOP will be submitted as requested by the 24th of July.	The inspector will ensure that the agreed date for submission of the outstanding risk assessment is reviewed on or before 24 July 2013, and action taken accordingly. Further action required
8. Background air quality The centre could not provide evidence that the background air quality in areas where the processing of gametes and embryos takes place, is of at least grade D air quality.(SLC T 20)	The PR should ensure that in premises where the processing of gametes or embryos exposes them to the environment, the air quality must be tested and documented, and achieve at least grade D air quality. A copy of the air quality sampling report for the andrology laboratory should be provided to the centre's inspector by 24 October 2013.	In May we commissioned a report to provide documented evidence that air quality results for the laboratory areas demonstrate compliance with HFEA requirements as referenced to The European Union Tissue and Cells Directives (EUTCD). The report confirmed that air quality in the lab and andrology meet HFEA requirements. A copy of the air quality	The inspector will ensure that the agreed date for submission of the outstanding air quality sampling report is reviewed on or before 24 October 2013, and action taken accordingly. Further action required

		sampling report for the andrology lab will be submitted by the 24th of October.	
9. Written information for gamete providers The written information for gamete providers did not contain all the HFEA requirements. It was not clear what information will be fed back to the gamete provider (SLC T97).	The PR must ensure that patient information is available, stating what information relating to the outcome of the donation will be made available to the gamete provider. A copy of the patient information is to be sent to the centre's inspector by 24 July 2013.	This document is in the process of being updated and will be submitted as requested.	The inspector will ensure that the agreed date for submission of the outstanding patient information is reviewed on or before 24 July 2013, and action taken accordingly. Further action required
10. Staff induction The centre has policies to support induction training, but there was no evidence that the local induction was employed in the laboratory for staff new to the centre (SLC T15).	The PR should ensure that all staff new to the centre, complete a formal induction to the centre.	As noted, policies are in place to support induction but had not been actioned for some of the laboratory staff new to the centre. We are in the process of ensuring that these members of staff have now completed their inductions. We are also currently having Q-pulse installed which we intend to use to facilitate further develop and standardisation of our training and competancy programmes.	The inspector is satisfied with the information submitted with the report. No further action.
11. Website	The PR should ensure that the	We are updating our figures	The inspector will ensure that

The centre's website is not compliant with Chair's Letter CH (11)02. The website does not show a comparison of the outcomes of treatment, for the centre, like with like against the national rate; for the same year, maternal age and treatment type.	centre's website satisfies the requirements of the Chair's Letter CH (11)02 by 24 October 2013.	and will ensure that our website complies with HFEA requirements by October the 24th..	the agreed date for checking the website is reviewed, on or before 24 October 2013, and action taken accordingly. Further action required
12. Standing operating procedures; 1. The centre's witnessing SOP does not document; a) the witnessing procedures for these process for egg freezing and thawing (SLC T33b). b) the process for the disposal of embryos (SLC T33b). 2. The centre does not have an SOP for the use of embryos for training staff, to ensure there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services. (SLC T95). 3. An SOP for measuring	The PR should ensure that there is an SOP to be followed for the five areas identified. Confirmation from the PR that this has been addressed should be sent to the centre's inspector by 24 July 2013.	Confirmation will be sent as requested.	The inspector will ensure that the agreed date for submission of the outstanding SOP is reviewed on or before 24 July 2013, and action taken accordingly. Further action required

background air in the laboratory should include a section on air quality particle counting (SLC T33b). 4. The centre does not have an SOP in place for the action to take in the event of equipment malfunction or failure. (SLC T33b**).**			
13. Consent to disclosure The HFEA register team reviewed 10 patient and partner registration forms, discrepancies were found between two completed patient/partner disclosure consents on patient files and the related consent data submitted by the centre for inclusion on the register. Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH (10)05 and Direction 0007.	The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 24 October 2013.	This procedure is currently being reviewed. The report and corrective actions will be submitted by the 24th of October as requested.	The inspector will ensure that the agreed date for submitting the report is reviewed, on or before 24 October 2013, and action taken accordingly. Further action required
14. Reporting requirements The HFEA register team found that out of a sample of 40 donor insemination cycles, there was one that had not been reported to the register by the inspection date. (Directions 0005. SLC T9 (e) / T41).	The PR should review the difference in reporting timescales for donor insemination cycles versus IVF cycles to ensure these cycles are reported within the timeframe specified in Direction 0005.	Reporting timescales for donor IUI, partner IUI, and donor IVF, partner IVF have been audited over a two month period. We are in the process of completing the audit summary and corrective actions. These will be submitted by the 24th of	The inspector will ensure that the agreed date for submitting the audit is reviewed, on or before 24 October 2013, and action taken accordingly. Further action required

	A summary report of the findings of the review, including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 24 October 2013.	October.	

Additional information from the Person Responsible
with reference to the multiple birth rate, our current multiple pregnancy rate (Oct 2012 to April 2013) is 12% of clinical pregnancies which is in line with the current target of 10% live multiple birth rate.

HFEA Executive Licensing Panel Meeting

5 July 2013

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

Minutes – Item 2

Centre 0109 – (Assisted Conception Unit, Kings College Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (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 medium sized centre which has held a treatment and storage licence with the HFEA since 1992.

2. The Panel noted that the centre is currently on a five year licence which expires on 30 September 2013.

3. The Panel noted that, in the 12 months to February 2013, the centre provided 602 cycles of treatment (excluding partner intrauterine insemination (IUI)).

4. The Panel noted that, for IVF and ICSI in the 12 months to December 2012, the centre's success rates are in line with the national averages.

5. The Panel noted that, between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 20%, and that this represented performance that was not likely to be statistically different from the 15% multiple live birth rate target for this period.

6. The Panel noted that this centre has one transport centre, Epsom and St Helier NHS Trust.

7. The Panel noted that, at the time of the inspection, the Inspectorate identified four major and 10 other areas of non-compliance.

8. The Panel noted that, since the inspection, the Person Responsible (PR) has resolved one major and one other area of non-compliance.

9. The Panel urged the PR to rectify the non-compliances, particularly the three outstanding major areas of non-compliance.

10. The Panel noted that the PR has given a commitment to fully implement the remaining recommendations made by the Inspectorate regarding the remaining areas of non-compliance.

11. The Panel noted the constructive engagement received by the HFEA from the PR regarding staff recruitment issues, and that it is reassured that the centre will work hard to rectify these.

Decision

12. 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.

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

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

15. 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.

16. The Panel urged the PR to address the Inspectorate's recommendations within the timescales stated in the inspection report.

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

Signed: JTizzard Date: 17 July 2013

Juliet Tizzard (Chair)