Renewal Inspection Report

ACU Kings College Hospital
0109

Date of Inspection: 15th April 2008
Date of Licence Committee: 7th July 2008

CENTRE DETAILS

Centre Name	ACU Kings College Hospital
Centre Number	0109
Licence Number	L0109-11-a
Centre Address	1st Floor Mapother House Kings College Hospital Denmark Hill London SE5 9RS
Telephone Number	0203 299 5390
Type of Inspection	Renewal
Person Responsible	Dr John Parsons
Nominal Licensee	Cathy Warwick
Inspector(s)	Ellie Suthers, Parvez Qureshi, Bryan Woodward
Fee Paid	Fee paid
Licence expiry date	30th September 2008
NHS/Private/Both	NHS and self funded

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About the Inspection:
This inspection visit was carried out on Tuesday 15th April 2008 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received since the last inspection.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Assisted Conception Unit (Unit) is part of Kings College Hospital, London and provides NHS and self-funded treatments to service users primarily from the South East of England. (Lambeth, Lewisham, Southwark, Greenwich, Bexley and Barnet Primary Care Trusts) The Unit has provided Donor Insemination treatment since 1975 and IVF treatment since 1983. The Unit also provides transport service arrangements with St Helier Hospital in Surrey.

The Person Responsible (PR) is Dr John Parsons, Consultant Obstetrician and Gynaecologist and accredited Consultant, who has been in post at Kings Healthcare NHS Trust since 1986 (Person Responsible Entry Programme completed 2008).

Activities of the Centre: (01/01/2007 – 31/12/2007)*

IVF	279
ICSI	234
FET	16
DI	46
Egg donation	4
Egg recipient	1

*This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. 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 Licence Committee

Kings College NHS Trust ACU is a moderate to large unit providing approximately 600 licensed treatment cycles per year. The unit appears to have suitably qualified and experienced staff and adopts appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment and service they receive. On inspection the unit appears to be suitably equipped, well organised and staffed appropriately for the level of activity. There is a good history of regulatory compliance.

Improvements should be considered in the following areas:

- Timely payment of HFEA invoices;
- Competency assessments;
- Compliance with witnessing procedures;
- Development of Standard Operating Procedures as part of the Quality Management System;
- Third party agreement to be in place for transporting cryopreserved material;
- Accuracy of the annual I.C.S.I records;
- Consent processes and documentation from satellite unit.

The inspection team recommends the renewal of the Unit's licence for five years without any additional conditions being imposed.

Risk Assessment

Following the renewal inspection on April 15th 2008 with information and data available to the HFEA inspection team, the risk score is assessed as 11%. This constitutes a low level risk status analysed by the HFEA Regulation Risk Assessment Tool Version 3.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		**x**	
2. Quality of the service		**x**	
3. Premises and Equipment		**x**	
4. Information		**x**	
5. Laboratory and clinical processes		**x**	

Breaches of the Act, Standard Licence Conditions or Code of Practice: The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The HFEA Finance Department noted that the Unit takes an average 59 days to pay HFEA invoices, which is an additional 31days to the payment terms of 28 days. (*CoP A.16.3)*	The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days.	By June 30th 2008
It was noted during the inspection that the embryologists when assisting with embryo transfers are performing the ultrasound scanning. There was no evidence of training or competency assessment. *(CoP 6.2.2 (b))*	The embryologist must be able to demonstrate training and competency assessments for ultrasound scanning.	By August 31st 2008
It was observed during the inspection that three dewars were not fitted with alarms. *(CoP S.6.4.2 (b))*	Alarms should be fitted to all dewars.	A timescale for the installation of alarms should be forwarded to the HFEA by 15 June 2008. In the interim, the risks of storing cryopreserved material without alarms should be

		assessed and measures implemented to moderate any risks.

Non-Compliance

Area for improvement	Action required	Time scale
It was noted that there is no third party agreement in place with the courier who provides transport for cryo-preserved material. *(CoP S.4.2.10)*	A documented third party agreement is required with a person or entity which provides products to a licensed centre that has the potential to affect the quality and safety of gametes or embryos.	By August 31st 2008
The figures reported for the annual records of clinical ICSI were found not to be accurate. *(CoP S.5.2.7)*	All annual ICSI data to be reviewed by the Senior Embryologist and corrections reported to the HFEA.	By the 31st of June 2008
Not all service user consent documentation from the transport centre was complete or had signatures (CoP S.7.5.4 (c))	The PR should review the consent process with staff at the transport centre to ensure all service user consent and documentation is complete	By the 31st of August 2008
During review of service user health records it was noted that on two occasions the doctors 'witness' signature was missing from the embryo transfer section of the records. It was noted that a number of embryologist signatures were not in the appropriate boxes on witnessing documentation. *(CoP S.7.8.15)*	Centres shall have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.	Immediately
Not all polices and procedures or laboratory Standard Operating Procedures (SOPs) are written and in place	The centre should implement a system that results in clearly defined and effective documentation and authorised standard operating procedures (SOPs), for the activities for which a licence has been granted (A.10.24)	31st August 2008

Recommendations	Time scale
The inspectors recommend a more formalised method off recording meeting minutes including meeting attendees and decisions made.	By the time of the next inspection.

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
Producing room for patients referred by their GP was considered unfit for purpose by the inspectorate. Improve the standards of the production room.	The production room has undergone minor cosmetic improvements (dimmer switch: pictures and repainted. There are plans for a major refurbishment but funding has yet to be agreed.
Pulse oximeters are recommended for the two recovery bays to provide additional monitoring for patients recovering from sedation.	Pulse oximeters have been provided for the two recovery rooms (observed by the inspection team 15th April 2008)
Ensure that the practice of laboratory staff "topping up the dewars" is not performed as a solo activity.	The inspection team were assured that two laboratory staff are always present when topping up the dewars.
Monitor and check Carbon Dioxide CO_2 gas cylinders daily	Carbon dioxide is now fed into the unit from an external storage unit in the grounds of the hospital with an automatic change over and alarm system if a cylinder goes empty.
Ensure that sperm samples and embryos are not stored together in the same dry shipper.	Sperm samples and embryos are now stored separately.
Staff accessing and using liquid nitrogen should wear safety goggles in the interests of health and safety.	Staff accessing and using liquid nitrogen are wearing safety goggles, gloves and laboratory coats.
Review and amend all policies and procedures to remove inconsistencies, and introduce a standard template for all policies and procedures including version control, date of issue and date of review.	All polices and procedures have been reviewed and amended to remove inconsistencies. A standard template is being introduced for all polices and procedures as part of the Quality Management System.
Devise an alternative means of notifying staff of patient arrival at the centre other than the use of the whiteboard system.	Staff are notified that service users have arrived by observing ticked off initials rather than first names on a white board in the waiting area.
Devise an alternative system for GP referred patients attending for semen assessment to leave their samples rather than walking through the unit.	GP referred service users attending for semen assessment leave their specimens in numbered locked cabinets at reception instead of walking through the Unit with their samples.
Ensure all laboratory staff attend a manual handling training course.	All laboratory staff have attended a manual handling course.

Document a centre specific induction programme for new starters.	A Unit specific induction programme has been documented for new staff.
Introduce training folders for all Unit staff. This should include evidence of competency "sign off".	Training folders are being introduced for all staff.

Additional licence conditions and actions taken by Unit since last inspection

Date	Action taken
	N/A

Report of Inspection findings

1.**Organisation**
Desired Outcome: The Unit is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
Leadership and management: The Person Responsible (PR) has completed the HFEA PR entry programme (PREP) and is considered appropriately qualified and experienced for the role. *(CoP: S.4.1.5: S.4.1.4)* The Senior Nurse, Service Manager, PR and the Senior Embryologist were present for the inspection and provided all the information requested both written and verbal. Each member of staff approached appeared to know about the inspection process and provided information and comment when asked. *(CoP: S.4.1.3)* Information provided by the staff demonstrated a documented, clear organisational structure both within the Unit and as part of the Kings College NHS Trust. During staff interviews an understanding of line reporting mechanisms was demonstrated. *(CoP S.4.2.5)* All staff interviewed during the inspection stated that they were content with the support received from senior management in the Unit and that there is a sufficient number of staff employed to manage the current activities. **Organisation of the Unit**: On the day of inspection the Unit appeared to be well organised and calm with posters informing service users of the inspection team's presence. The in-date HFEA licence and the Patient Advisory Liaison Service (PALS) complaints procedure were clearly displayed in the service user waiting area. Staff interviewed during the inspection assured the inspectors that they are kept informed of the day-to-day activities, changes and developments within the Unit. Raising concerns or suggesting improvements by staff is actively encouraged through multi-disciplinary, regularly scheduled meetings. Some meeting minutes were made available to the inspection team; they showed regular scheduling of meetings and staff participation. *(CoP S.6.2.13)*

The PR, senior nurse and senior embryologist confirmed that members of staff are qualified for the roles they perform and that qualifications have been confirmed in line with the Kings Healthcare NHS Trust recruitment and training policies. The inspectors observed evidence of staff completing annual mandatory training, professional updates and continued professional development in individual staff training logs. *(CoP S.6.2.1)*. Evidence was seen by the inspector of competency assessments and supporting documentation for the nursing staff. *(CoP 6.2.2(b))*

Risk Management:
The Unit follows the Trust polices for risk management and clinical governance and has access to meeting minutes from the respective committees. Evidence of these minutes was observed at the time of inspection. Evidence was seen of ten ACU specific risk assessments carried out since the last inspection and three health and safety risk assessments required by the Kings College Hospital NHS Trust.

Incident Management:
The inspectors observed a documented procedure for the identification, investigation, control and recording of adverse incidents including the requirements for reporting to the HFEA. The documentation was seen to be up to date and complete. Staff demonstrated their knowledge and understanding of the incident procedures during interviews with inspectors and observed in discussions recorded in Unit meeting minutes. Staff attend the gynaecology risk meetings where incidents are discussed across the directorate, as part of corporate risk management, using service users initials to maintain confidentiality *(CoP S.9.4.1)*

Contingency Arrangements:
The PR informed the inspection team that there are written contingency arrangements in place with Guys and St Thomas' NHS Trust. The PR informed the inspector that these arrangements are in the process of being formalised into signed agreements.
(CoP S.6.3.4 (b)) Kings College NHS Trust provides emergency facilities back-up for electricity and medical gas supply.

Areas for improvement

Payment of treatment fees:
The HFEA Finance Department noted that the Unit takes an average 59 days to pay HFEA invoices, which is an additional 31days to the payment terms of 28 days. (*CoP A.16.3)*

Competency Assessments
It was noted during the inspection that the embryologists when assisting with embryo transfers are performing the ultrasound scanning. There was no evidence of training or competency assessment. *(CoP 6.2.2 (b))*

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection
None

Evaluation
Some improvements required

2. Quality of service
Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:
1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates

1st of April 2003 – 31st March 2006

Age	DI %		FET%		IVF/ICSI%	
< 35	14	N/D**	18	N/D	21	Sig below
35-37	10	N/D	12	N/D	17	N/D
38-39	11	N/D	5	N/D	11	N/D
40-42	6.25	N/D	14	N/D	9	N/D
>42	0	N/D	12.5	N/D	0	N/D

*"This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. 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."
**N/D no difference to the national average

Areas of firm compliance

Quality Management System: (QMS)
The PR and staff have demonstrated a commitment to the establishment and maintenance of a QMS. The system is in the process of being developed with input from all members of staff. *(CoP: S.4.2.1).* The Quality Manager, who is also the Service Manager, is leading and coordinating the development and implementation process. The system was paper based at the time of inspection but there are plans to transfer to an electronic system over the summer of 2008. The inspector observed a detailed quality manual with document and version control and a description of the Unit and services provided. *(CoP S.5.2.3: S.5.2.4)*
Some of the policies and procedures contained in the quality manual were observed to be up to date, version-controlled and regularly reviewed. Some Standard Operating Procedures (SOPs) for laboratory processes need to be written and quality controlled. These are outlined in section 5.

Monitoring and resolution of complaints:
The Unit has a written procedure in place for the acknowledgment and investigation of complaints, as well as collecting suggestions and compliments from service users. There is a designated individual who has responsibility for the management of complaints. The complaints process is facilitated through the Patient Advisory Liaison Service (P.A.L.S) based at the Trust. Inspectors observed that records of complaints and their investigation together with the corrective action are kept in the Unit. A verbal complaints policy is in place. *(CoP*

S.9.2.2).
An audit of six patient questionnaires returned to the HFEA showed a high level of service user satisfaction and no complaints were raised from the questionnaires.

Staff Suggestions:
Staff suggestions and participation in day-to-day changes and new developments are demonstrated in meeting agendas and minutes. This was corroborated by staff interviewed by the inspection team. *(CoP S.9.2.3)*

Areas for improvement

The centre should implement a system that results in clearly defined and effective documentation and authorised standard operating procedures (SOPs), for the activities for which a licence has been granted (A.10.24)

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Quality objectives and plans

Evaluation

Some areas for improvement

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
The Unit is located on the first floor of Mapother House which is part of the Kings College Hospital NHS Trust campus. The Unit is self contained with a number of secured access points. The main door to the Unit is locked and alarmed out of hours ensuring security. During the inspection it was noted that the HFEA licence, complaints process and an advertisement for a service user open evening were all displayed clearly on a notice board in the reception area. The reception desk allows the receptionist a clear view of everyone entering or leaving. There are a number of small locked cabinets on the wall of the main entrance into which service users referred by their GPs place sperm samples for collection by the embryologist. Administrators, secretaries and the receptionist work in the main administration area, which also contains filing cabinets in which service user health records are stored. This area has extra out of hours security in a locked “drop down” grill over the front of the reception desk. Clinical facilities are located on a single central corridor running the length of the unit. These facilities include two consulting/treatment rooms, one operating room, two recovery rooms, laboratories, offices, waiting areas and storage space. Staff have two extra consulting rooms available to them along the corridor from the main Unit if required at busy times. These are rarely used. The entrance to the cryostore is located on this corridor. The cryo store was seen to be locked on the day of inspection. The room is well ventilated and was seen to provide suitable facilities for the storage of gametes and embryos. *(CoP S.6.3.8)* On the day of inspection the Unit appeared to have premises and facilities suitable for the activities for which it is licensed including facilities for staff, reception, administration, clinical and counselling activity, laboratory work, storage of gametes and embryos. (*CoP S. 6.3.2)*

Counselling Facilities:
The room provided for counselling is located in a quiet section of the Unit and was observed to be quiet and comfortable in which sessions can be held that are private, confidential and without interruption. Alternative facilities are available in the Department of Psychology as is contingency counselling support if the Unit counsellor is absent (*CoP S.6.3.5)*

Staff facilities:
The Unit provides suitable and appropriate facilities for staff including basic catering facilities and locked storage for personal belongings. *(CoP S.6.3.13)*.

Laboratory Facilities:
During inspection and in discussion with staff the laboratory facilities appear to be appropriate for the activities carried out in them. The cryostore was seen to be appropriate for the volume and activities conducted in it. Emergency procedures were seen to be in place to deal with damage to storage dewars. There is a staff rota in place to respond to emergencies. *(CoP.S.6.3.8)*

Management of equipment and materials:
All key pieces of equipment were seen to be CE marked. Annual and daily servicing and maintenance records for equipment was observed to be in place and complete. *(CoP S.6.4.1: S.6.4.2)*

Air Quality:
The air quality in the laboratory is monitored every 6 months and documentation was seen by the inspector to show acceptable air quality. *(CoP S.3.6 (b))*

Areas for improvement

Storage facilities for gametes and embryos:
It was observed during the inspection that three dewars were not fitted with alarms. Alarms should be fitted as soon as possible. *(CoP S.6.4.2 (b))*

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Evaluation

Some improvements required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
General information: Display boards in the access corridor and main reception area have posters showing the Unit's in-date HFEA Licence. Also displayed are various information leaflets including information about the Trust Patients Advice and Liaison Service. (PALS) the procedure on how a service user can make a complaint and the availability of service user information evenings. The service user information submitted as part of the inspection process has been reviewed by the inspection team and appeared to contain required information in a simple to read format. During the inspection staff informed the inspectors that all information in the service user information material is discussed in depth at the time of consultation. *(CoP S.7.4.1)* **Meetings and communication:** The Unit holds weekly general and administration meetings which all appropriate staff are required to attend: The agenda was seen to include: day to day clinical updates: changes in buildings and facilities: pregnancy rates and HFEA Alerts. Dated minutes were observed by the inspection team. The unit appears to have an effective means of communicating information to staff. It was agreed by the PR at the time of inspection that the method for recording minutes and demonstrating the decision making process could be improved by generating complete minutes rather than making informal notes in a hard back notebook. *(CoP S.6.2.13)*

Confidentiality and access to health records:
The Unit is part of the Kings Healthcare NHS Trust and follows the policies and procedures of the Trust in order to ensure information provided in confidence by service users is kept confidential. *(CoP S.7.2.1)* Health records were seen to be stored securely in well organised filing cabinets in the main administration area. This area is out of the main service user areas, is staffed during work hours and locked and alarmed out of clinic hours. Archived health records are stored in an offsite commercial facility *(CoP G.10.2.1)* During the inspection the member of staff responsible for maintaining the records library demonstrated a practical knowledge of records management, storage and confidentiality.
All visitors to the Unit, students, Trust staff, visiting clinicians etc are required to sign a confidentiality declaration before accessing the premises. Service users do not have a hospital number and are not on the main hospital administration system confidential information can not be accessed by non ACU staff members.

Information for service users/consents:
Service user information received prior to inspection, during inspection and discussed during interviews with staff appears to show that the Unit ensures that before individuals give consent to treatment they are given appropriate information on which to make their decision on treatment. *(CoP S.7.4.1)* This was corroborated during interviews with three service users who confirmed they had received sufficient understandable information. All consent to treatment is currently taken by doctors on the first consultation.
Documented procedures are in place to ensure verification of the identity of service users: passports, signatures and National Health Service (NHS) numbers are required from service users before treatment is started. *(CoP S.7.5.2*)
On examination of ten service user records it was observed that all Kings College Hospital NHS Trust ACU consent forms were completed appropriately but that two consent forms completed at the satellite centre were incomplete. This was brought to the attention of the PR.

Welfare of the Child information:
Completed Welfare of the Child assessment forms were observed in ten sets of service users' health records and staff demonstrated an understanding of requirements during interview with the inspectors. The senior nurse informed the inspector that any issues or concerns of Welfare of the Child are discussed at weekly multi disciplinary meetings. If issues are raised during counselling the counsellor will raise it with the PR and a team decision will be made on any actions. *(CoP S.7.1.3: S.7.6.4)*

Donor information:
Women seeking to donate eggs are provided with information and care by a designated coordinator. Information provided by the Unit and reviewed by the inspector appeared to provide clear and relevant information for potential donors.*(CoP S.7.6.6: S.7.6.7)*

Traceability and coding:
During the inspection the inspector observed documented procedures in place to ensure that all gametes and embryos and materials which come into contact with gametes and embryos are traceable, including identification codes, from procurement to disposal. Discussion with staff during interview confirmed the procedures are adhered to by staff. *(CoP S.7.3.1)*

Areas for improvement

Third party agreements:
It was noted that there is no third party agreement is in place with the courier who provides transport of cryopreserved material. A documented third party agreement is required with a per or entity which provides a product (a service, software, hardware or materials) to a licensed centre that has the potential to affect the quality and safety of gametes or embryos (S.4.2.10).

ICSI Annual reports:
The figures reported for the annual records of clinical ICSI were found on inspection not to be accurate. The senior embryologist agreed to recalculate the figures and report the correct figures to the HFEA.

Consent documentation:
Consent documentation for service users referred from St Helier Hospital was not completed. One set of records had a signature missing. One set of records had not ticked any boxes on posthumous consent for the use of material. The PR agreed that he would review the consent process with the staff at St Helier Hospital as all consent taking should be done by staff at Kings ACU.

Areas for consideration

Some meeting minutes are recorded in a diary stored in the service managers' office. These minutes did not contain meeting dates, attendees or signatures. It was recommended that a more formalised method of recording meeting was developed in order to enable the Unit to demonstrate a decision making process. (S.6.2.13)

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.

Areas not covered on this inspection

Surrogacy
Home procurement report documentation

Evaluation

Some improvements required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory processes
2. Selection and validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	3.5
NMC registered nurses	5
HPC registered scientists	1.8
Scientists working towards registration	3
Support staff (receptionists, record managers, quality and risk managers etc)	Administration 6
Counsellors	0.3

Summary of laboratory audit / Audit of records
The last storage audit was completed in December 2007: There four discrepancies were identified and rectified following the audit: all of the discrepancies were documentation errors.
Summary of spot check of stored material
On the day of inspection one embryo was tracked from records to the tank and vice versa: no discrepancies were found. One sperm sample was tracked from records to the tank and vice versa: no discrepancies were found.
Areas of firm compliance
Staff training and competencies: Evidence was seen during the inspection that all members of staff have attended a Trust induction programme. Interviews with staff demonstrated evidence of some competency assessments as well as continuing education and professional development *(CoP S.6.2.9 & S.6.2.11)* evidence of which was seen in training logs. All nurses work in the operating theatre and recovery area. Three nurse training logs were seen, each of which were up to date, complete and well ordered. Staff from the Unit attends the Trust induction programme as evidenced in individual training logs. *(CoP G.13.6.1)* Documented evidence was observed of participation in the UK National External Quality Assessment Service (NEQAS) for sperm analysis. All embryologists participate in the scheme and results are analysed for intra staff comparisons. *(CoP S.7.8.1)* All scientists working in the

laboratory are either registered with the Health Professional Council (HPC) or are working towards registration.

Counselling:
The inspector observed that counselling facilities are provided in quiet, comfortable, private and confidential surroundings. *(CoP S.6.3.5)* During interview the Senior Nurse informed the inspector that counselling is provided independently of clinical decision making and that counselling records are not stored in clinical health records. Counselling is made available to all service users seeking treatment and appointments can be made either by the Unit staff or can be self referred.

Validation of laboratory procedures:
During the inspection the laboratory staff provided evidence that laboratory procedures have been validated as per the requirements of the Code of Practice *(CoP S.7.8.3)*

Packaging and Distribution:
It was observed during the inspection that procedures are in place to ensure that gametes are packaged and distributed in a manner which ensures safety and quality and reduces the possibility of undetected tampering. *(CoP S.7.7.11: S.7.7.12: S.7.7.13)*

Areas for improvement

Witnessing:
During review of service user health records it was noted that on two occasions the doctors 'witness' signature was missing from the embryo transfer section of the records.
It was noted that a number of embryologist signatures were not in the appropriate boxes on witnessing documentation. Witnessing should be carried out at contemporaneously with a procedure and confirmed with a signature.
(CoP S.7.8.15)

Standard Operating Procedures:
It was observed during the inspection that a number of Standard Operating Procedures (SOPs) need updating in order to achieve quality management standards. These include:

- Disposal of embryos;
- Topping up the liquid nitrogen dewars;
- Ensuring transport dewars are empty before use;
- Flagging the use of donor sperm that may be reaching the 10 family limit;
- The handling of viral positive gametes.

As part of the development of the Quality Management System all SOPs and laboratory documents need to be finalised and indexed. The senior embryologist assured the inspector that this process should be completed by 31st May 2008. *(CoP S.5.2.2)*

Areas for consideration

None

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas of improvement cited above.
Areas not covered on this inspection
None

Evaluation
Some improvements required

Report compiled by:

Name…….

Designation…….

Date……

Appendix A: Centre Staff interviewed

Dr John Parsons – Persons Responsible
Seven members of ACU staff
Three service users

Appendix B: Licence history for previous 3 years

L0109/11/a
Treatment with storage 05/07/2007 – 30/09/2008
Variation of Licence to include new EUTD Conditions
No conditions.

L0109:10/a
Treatment with storage 01/10/2005 – 30/09/2008
Current Licence.
No conditions.

L0109/9/c
Treatment with storage 27/06/2004 – 30/09/2005
Removal of conditions

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR…….

Date of Inspection……..

Date of Response……

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name…….

Date……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Factual inaccuracies have been amended in the report.

2. Please state any actions you have taken or are planning to take following the inspection with time scales

Page 21 Standard Operating Procedures Some of the updates are already in place for the outstanding SOPs: • Disposal of embryos: currently included in the 'Embryo Transfer' SOP • Topping up liquid nitrogen dewars: included in the lab protocol book and being transformed into an SOP • Ensuring transport dewars are empty before use: this will be included in SOP 'Transport of gametes and embryos nationally and internationally' • Flagging the use of donor sperm that may be reaching the 10 family limit: all of the donors currently being used are from our own donor sperm bank and the card system that we use contains the pregnancies clearly highlighted. However, it will be included in SOP for donor sperm matching. • The handling of viral positive gametes: we currently have an SOP for this matter, including the handling of embryos and their transfer into patients.

BREACH	ACTIONS	TIMESCALE
The HFEA Finance Department noted that the Unit takes an average 59 days to pay HFEA invoices, which is an additional 31days to the payment terms of 28 days *(CoP A.16.3)*	Discussions to take place with the Head of Financial Accounts and Processing to identify barriers to prompt payment and to take steps to ensure fees are paid within 28 days.	By 30th June 2008
It was noted during the inspection that the embryologists when assisting with embryo transfers are performing the ultrasound scanning. There was no evidence of training or competency assessment. *(CoP 6.2.2 (b))*	A training programme and competency assessment for ultra sound scanning is to be set-up. This will include certification once completed.	By August 31st 2008
It was observed during the inspection that three dewars were not fitted with alarms. *(CoP S.6.4.2 (b))*	All dewars in the cryo room are now alarmed. The 2 dewars in the sperm area cannot be fitted with alarms because of their size. They are topped up with liquid nitrogen every day and this is signed for. They are for holding embryos while waiting for blood test results, which should occur within 24h as soon as the new computer system is in place. These embryos were previously held together with sperm in an un-alarmed dry shipper which constituted a much higher risk. A risk assessment of storing cryopreserved material without alarms will be made and measures implemented to manage any risks.	By 30th Sep 2008

Non-Compliance

Area for Improvement	Action	Timescale
It was noted that there is no third party agreement in place with the courier who provides transport for cryo-preserved material. *(CoP S.4.2.10)*	A documented third party agreement was requested and has been received.	By 31st August 2008
The figures reported for the	All annual ICSI data to be	By 31st of June 2008

annual records of clinical ICSI were found not to be accurate. *(CoP S.5.2.7)*	reviewed by the Senior Embryologist and corrections reported to the HFEA.	
Not all service user consent documentation from the transport centre was complete or had signatures (CoP S.7.5.4 (c))	The PR will review the consent process with staff at the transport centre to ensure all service user consent is valid and documentation is complete.	By 31st August 2008
During review of service user health records it was noted that on two occasions the doctors 'witness' signature was missing from the embryo transfer section of the records. It was noted that a number of embryologist signatures were not in the appropriate boxes on witnessing documentation. *(CoP S.7.8.15)*	Witnessing protocols are currently in place. However, the documentation for the clinician witness is to be moved to reduce instance of failure. An audit of accuracy of completion will then be conducted once a quarter. During the witnessing audit previous to the inspection signatures in the wrong boxes were not observed. However, as a result of the HFEA inspection finding, this has been brought to the attention of the lab team and both witnesses now check that the signature is in the appropriate box at the time of signing.	By 30th Sept 2008
Not all polices and procedures or laboratory Standard Operating Procedures (SOPs) are written and in place	All standard operating procedures (SOPs) and policies for the lab are in the process of being approved.	By 31st August 2008

Recommendations	**Action**	**Timescale**
The inspectors recommend a more formalised method off recording meeting minutes including meeting attendees and decisions made.	Management meeting minutes are to be typed up and include meeting attendees and decisions made.	By 30th June 2008

COMMENTS

Page 13 - Live Birth Rates

Our current clinical pregnancy rate for women less than 35yrs is significantly better than during the period chosen for the inspection report. We feel that the comments below the data should refer the reader to the HFEA website for more recent relevant data

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

7 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

ACU Kings College Hospital (0109)
Licence Renewal

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
Sally Cheshire, Lay Member	Claudia Lally, Committee Secretary
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Observing:
Neva Haites, Professor of Medical Genetics, University of Aberdeen	Bhavna Mehta, Inspector
	Angela Sutherland, Inspector
	Providing Legal Advice to the Committee:
	Graham Miles, Morgan Cole

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

The following papers were considered by the Committee:

- papers for Licence Committee (38 pages)
- no papers were tabled.

1. The papers for this item were presented by Ellie Suthers, HFEA Inspector. Ms Suthers informed the Committee that this centre provides NHS and self-funded treatments to service users from the South East of England. It is a large to moderate unit providing in the range of 600 licensed treatment cycles per year. Ms Suthers reported that a number of areas for improvement were identified at the inspection and these are listed at pages 6 to 8 of the report. Ms Suthers described the actions which had taken by the Person Responsible to address the findings of the inspection team.

2. Ms Suthers reported that the late payment of invoices had now been resolved following discussion with the Head of Financial Accounts and Processing to ensure prompt payment. The centre has also implemented competency training for embryologists who assist with embryo transfers. On

the issue of the un-alarmed dewars Ms Suthers reported that all the dewars in the cryostore are now alarmed and though the centre has 2 dewars in the sperm area which cannot be fitted with alarms because of their size, the centre has a comprehensive policy and procedure in place for ensuring daily topping-up of liquid nitrogen and will be conducting a risk assessment.

3. Ms Suthers reported that the centre is 90% through its review of SOPs and is on track to complete this by 31 August.

4. Ms Suthers reported that third party agreements with the courier who provides transport for cryopreserved material is now in place.

5. In relation to the inaccuracies in the reported annual figures for ICSI, Ms Suthers reported that a mathematical error was to blame and that the centre will be providing training to all its ICSI practitioners to ensure that there is no repeat.

6. Ms Suthers reported that the issues with user consent documentation had been discovered to originate at St Hellier, which is a satellite centre for the ACU. The Person Responsible will be considering how to address this problem and whether it is appropriate for consents to continue to be taken at St Hellier.

7. Ms Suthers reported that minutes are now taken at all meetings and that all the recommendations from the previous inspection have been carried out. She added that the recommendation of the Executive is that the centre's licence is renewed for a period of five years, with no additional conditions.

The Committee's Decision

8. The Committee noted that the Person Responsible had requested that the report to more precisely reflect the issues identified with the witnessing SOP and agreed that this would be done.

9. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

10. The Committee noted that the licence fee had been paid and agreed to renew the centre's licence for a period of 5 years with no additional conditions.

Signed…… … Date……..
Walter Merricks (Chair)