Interim Inspection Report

ACU Kings College Hospital
0109

Date of Inspection: 13th February 2007
Date of Licence Committee: 23rd May 2007

TRIM: 06/5619

CENTRE DETAILS

Centre Address	1st Floor Mapother House Kings College Hospital Denmark Hill London SE5 9RS
Telephone Number	0207-346-5390
Type of Inspection	Interim Inspection
Person Responsible	Mr John Parsons
Nominal Licensee	Catherine Warwick
Licence Number	L0109/10/a
Inspector(s)	Tony Knox (Lead Inspector)
	Brian Woodward
	Tahir Hussain
Fee Paid - date	Not Due
Licence expiry date	30th September 2008

Index

Page

About the Inspection:
This inspection visit was carried out on 13th February 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between January and December 2006.

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 interim 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, recommendations 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.

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 centre is part of the Kings College Hospital NHS Trust and provides NHS and self funded treatments to patients primarily from the South East of England. The centre has provided DI treatment since 1975 and IVF treatment since 1983. The PR estimated that approximately 50% of the patients treated are funded by the local Primary Care Trusts (PCTs) of Lambeth, Lewisham, Southwark, Greenwich, Bexley and Barnet.

The centre provides no satellite services. However it does provide transport service arrangements with St. Hellier Hospital in Surrey.

Activities of the Centre

Figures given below are taken from HFEA data between January 2005 and December 2005

Licensed treatment cycles	IVF ICSI FET Egg donation Egg recipient	259 335 39 11 8
Donor Insemination		122
Unlicensed treatments	IUI Ovulation Induction with IUI Surrogacy	
Research	None	
Storage	YES	

Summary for Licence Committee

The centre was seen to be well organised and staffed appropriately for the level of activity currently undertaken at the unit. There is a good history at the centre of Regulatory compliance, and the staff have developed a detailed program of activity to ensure compliance with the EU Tissue and Cells Directive.

The inspectorate recommends the continuance of the centre's license without additional conditions being imposed.

Risk Assessment

The centre had been awarded a risk score of 21% pre-inspection. The risk score following this inspection was recorded at 16%

The unit follows the Trust policies and procedures for risk management, and since the time of the last inspection, fire and clinical incidents had been risk assessed by the unit staff.

The Service Manager has been approved to attend a five day health and safety course later in the year, after which additional focus will be given to conducting further risk assessments.

A detailed self assessment document was forwarded to the HFEA prior to the inspection. The assessment made by the inspectorate during the inspection finds that this is consistent with the findings in the self assessment document.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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 or Code of Practice

Breach	Action required	Time scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
Producing room for patients referred by their GP was considered unfit for purpose by the inspectorate.	Improve the standards of the producing room.	As soon as possible

Recommendations	Time scale
Pulse oximeters are recommended for the two recovery bays to provide additional monitoring for patients recovering from sedation.	Immediate
Ensure that the practice of laboratory staff “topping up the dewars” is not performed as a solo activity.	Immediate
Monitor and check Carbon Dioxide CO_2 gas cylinders daily.	Immediate
Ensure that sperm samples and embryos are not stored together in the same dry shipper.	Immediate
Staff accessing and using liquid nitrogen should wear safety goggles in the interests of health and safety.	Immediate
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.	By end April 2007 and ongoing.
Formalise the centre’s contingency plan by producing a documented service level agreement.	As soon as possible
Produce a formally documented service level agreement between the centre and the transport unit.	As soon as possible
Devise an alternative means of notifying staff of patient arrival at the centre other than the use of the whiteboard system.	As soon as possible

Devise an alternative system for GP referred patients attending for semen assessment to leave their samples rather than walking through the unit.	As soon as possible
Ensure all laboratory staff attend a manual handling training course.	As soon as possible
Document a centre specific induction program for new starters.	As soon as possible
Introduce training folders for all centre staff. This should include evidence of competency "sign off".	As soon as possible

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
None	

Additional licence conditions and actions taken by centre since last inspection

C	**None**
A	**Complied Y/N**

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
All staff interviewed during the inspection stated that they were happy with the support received from senior management at the centre. There is a clear organisation structure of which all staff are aware. All staff interviewed stated that there were sufficient numbers of staff employed to manage the current activities of the unit. The centre follows the Trust policies for clinical governance and clinical risk. A Clinical Governance and Risk Committee has been set up for the hospital which meets monthly. Minutes from the meetings are taken and distributed throughout the hospital. Evidence of these minutes was seen during the inspection. The PR reports all incidents in accordance with the requirements of the HFEA. The incident policy is clear and all staff interviewed were aware of the process for reporting. A detailed action plan for the implementation of the European Union Tissues and Cells Directive (EUTD) requirements was provided to the inspectorate, and there was evidence provided to show that this is being followed. Work has commenced to introduce a quality management system to the centre. The Service Manager stated that a Quality Manager has been temporarily appointed to assist with this until April 2007, after which, budget has been approved to hire a specific Quality Manager/Nurse. Payments are made on time to the HFEA Finance Department.
Areas for improvement
The PR stated that there is as yet no formal documented contingency plan in place for the unit. However, there is verbal agreement that should the situation occur, patients whose treatment could not be safely stopped would be transferred to Guys Hospital fertility unit. It was agreed by the PR that a formal service level agreement (SLA) should be documented to

reflect this.

The centre provides Transport service arrangements for the St. Hellier Hospital, Carshalton, Surrey. It was noted that no formal SLA was in place for the provision of these services. It was agreed by the PR that this should be formerly documented.

A recommendation was made for the evening Monday meetings to be brought forward in the day (possibly lunchtime) which may improve staff attendance from all areas of the Clinic.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
Graphs produced from data provided to the HFEA prior to the inspection show that success rates for IVF and ICSI in most age groups were below the national average. The same is reflected in age group 40 to 42 for frozen embryo replacement. Success rates for donor insemination were above the national average, and ovarian hyper-stimulation syndrome (OHSS) rates were statistically insignificant. It was noted that these statistics were obtained from figures held on the HFEA register for the period 31st March 2002 and 1st April 2005. This was discussed with the PR. He reported that for a period of time, there had been no lead embryologist within the unit. This was rectified in 2005 with the arrival of the current head of embryology. In addition, he reported that for a six week period between March and May 2006, success rates were exceptionally poor. Despite a series of audits being performed at the time to isolate the reason for this, none had been discovered. It was reported that during the same period of time, laboratory desking had had to be cut to accommodate a new Class II hood. It was stated that these changes may have adversely affected the atmosphere within the laboratory and therefore impacted upon success rates although this could not be proven. In addition, all core staff within the unit changed between 2004 and the end of 2005 as rumours were circulating that the unit may have to close. Since the arrival of the lead embryologist, success rates have been steadily improving. Figures presented to the scientific inspector show that current success rates for all areas are now above the national averages. This will not be reflected however in the HFEA data due to the reported timescales.
Areas of firm compliance
Evidence was seen in the patients' notes that appropriate 'Welfare of the Child' assessments had been conducted. The patients' notes are housed in the area behind the main reception desk where the unit administration and secretariat work. Although it was noted that the filing cabinets used to house the notes were not locked, the area itself is secured by a locked door at the one end and by a roll down security tambour (which is also locked at night) by the

reception desk itself. This area is independently alarmed and linked to the main alarm system. This was considered suitable by the inspectorate.

Patients are assessed using the centres own protocols, which were considered fit for purpose by the inspectorate, and in accordance with funding guidelines from the various PCTs.

Any potentially difficult patient cases are discussed primarily at a multi-disciplinary team meeting. Where general consensus cannot be reached, these cases are referred to an Ethics Committee. Minutes taken at these meetings were evidenced.

The complaint policy provided to the inspectorate is clearly written and all staff interviewed were aware of the process required for reporting complaints. Three complaints have been received since the last inspection and all have been dealt with appropriately. A verbal complaints policy is also in operation.

A centre specific patient questionnaire has been devised and is in use within the unit. An audit of the completed questionnaires (36 responses from September to November 2006) had been compiled and was evidenced by the inspectorate during the visit. During her interview, the Service Manager reported that comments made in the questionnaires concerning improvements that could be made are discussed and where possible, improvement actions are taken.

Counselling is independent and provided free of charge to patients. The facilities used for counselling were evidenced and were considered to be fit for purpose by the inspectorate.

All donors are assessed and screened in accordance with the unit's policies and procedures which were considered fit for purpose by the inspectorate. Donor sperm is occasionally imported for use with named patients. All imports have been documented and actioned appropriately.

Areas for improvement

After registering attendance at the main reception, patients walk around the corridor (used as the centres waiting area) to a whiteboard where all patients' names are written for that day. Patients tick off their name on this board and then wait to be called. Whilst it was understood that this system provides benefits for the staff in knowing which patients' have arrived, its location in the corridor (within the unit), also shows other patients who is attending for treatment. This is considered to be a risk to confidentiality. This is further highlighted in the fact that male patients referred by their GP's for semen analysis only, have to pass the board in order to leave their specimens at the embryology laboratory for testing. Despite the PR noting that this had never been raised as an issue by patients in the past, it was recorded that this constitutes a breach of confidentiality and an alternative, less public system be introduced for staff.

Executive recommendations for Licence Committee

Recommendation to amend practice of displaying patient names in corridor to further protect patient confidentiality.

Areas not covered on this inspection
Egg sharing and surrogacy Protection of children arrangements

Evaluation
Some improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The unit was well signposted. The unit is housed within Mapother House, a separate building to the main hospital, and is shared by other medical disciplines. The door to the unit is locked and alarmed ensuring the security of the centre out of hours. A complaints poster, the centres licence, counselling poster, advertisement for the open evenings held and a patient questionnaire box were seen in the reception area of the unit. The reception desk allows the receptionist clear view of everyone entering the unit. Administration, secretaries and the receptionist work in this area, which also houses the patients' notes. These are stored in filing cabinets. There have been no changes to the premises since the last inspection, and all areas (with the exception of an additional room, just outside the unit, used as a male producing room for GP referred patients requiring only a semen analysis to be performed), were considered fit for purpose by the inspectorate. Storage dewars are housed within the embryology laboratory. All dewars were appropriately alarmed with access into the laboratory secured by both key lock and a digital key pad lock. A low oxygen alarm was also seen to be in place. There is a back-up generator in place which is tested weekly by the hospital maintenance department. A service log is kept showing when maintenance of all critical equipment is performed which was evidenced during the inspection. Incidents are reported in accordance with both HFEA requirements and the units own protocols. Between the last inspection and this inspection, the centre has reported ten incidents, all of which have been appropriately dealt with and have been "closed" by the HFEA. An emergency trolley was situated in the corridor outside the main treatment room where egg collections, replacements and IUIs are performed. It was evidenced that this had been checked daily. Although a defibrillator was not available on the unit, centre staff advised that one was located on the ward below the unit and would be used if required. Evidence was seen that portable appliance testing of equipment had been performed in December 2006.
Areas for improvement
A separate producing room to the one used by fertility patients is provided for patients attending the unit for semen analysis only. These patients are referred from their GP surgery.

The producing room is just outside the doors to the main unit. This was considered by both the inspectorate and the unit staff to be unsuitable. In addition, after producing a sample in this area, the patient transports the sample into the unit, reports to the reception desk and is then directed around the corridor (used as a waiting area for the fertility unit patients) to deposit the sample at the embryology laboratory. Centre staff were advised to devise an alternative system preventing access to the remainder of the fertility unit to these patients.

Following egg collection procedures, patients are moved to one of two recovery rooms across the corridor from the main treatment room. Although a nurse call bell system is in operation within both rooms, it is recommended that additional pulse oximeters be purchased to monitor patients recovering from their sedation.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered

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:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Sixteen sets of patient records were checked during the inspection. Seven sets of records were noted as containing errors relating primarily to incomplete consent forms and incomplete witnessing checklists. (It was noted by the scientific inspector that all witnessing records maintained in the laboratory were complete and in accordance with witnessing directions). It was noted by the Service Manager that an audit of patient notes for consents had been initiated and was currently ongoing. Errors found were being rectified with the patients.
Areas of firm compliance
The staff use the IDS patient database to store patient treatment information. Use of the system is restricted to authorised personnel only, with each member of staff being allocated a password. A backup is taken of the information each evening which is then stored securely. HFEA Registry Department reported no problems with data submission and updates. A small filing cabinet is used to hold all current patient information and treatment/consent forms which is maintained by the Service Manager and Quality Manager. Staff only use forms from this filing system to give to patients. Following a change to any of the documentation, the Service Manager or Quality Manager ensure that the old documentation is removed and replaced with the new. This ensures that only up to date documentation is used.
Areas for improvement
A large number of policies and procedures were submitted for review prior to the inspection. Whilst the majority of these were considered fit for purpose by the inspectorate, a number of inconsistencies were also noted. Examples of these inconsistencies included the “Clinical Protocol for IVF and ET”, where both the old 006 and 007 consent forms and new MT and WT consent forms are given to patients to complete. These were brought to the attention of the PR during the interview who reported that these would be changed. The policies and procedures submitted for review were seen as being in different formats. It was explained by the Service Manager that all policies and procedures (approximately 500) are in the process of being reviewed and amended to be on a standard template. It was further reported that the new documents will be version controlled and dated. The Service Manager estimated that this project will be completed by April 2007.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

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:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3 x Consultant Grade 2 x Specialist Registrar positions 2 x Clinical Fellows
NMC registered nurses	7
HPC registered scientists	1
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	8 (1 x Service Manager, 1 x administrator, 3 x secretaries, 2 x receptionists and 1 x independent counsellor).

Summary of laboratory audit
An audit of all dewars was conducted between 12th and 13th December 2006. An undisclosed number of errors were reported from the three dewars used to store donor sperm. Some samples had been transferred from the quarantine tank to the cleared dewars without amending the file system. These errors were rectified. Of the remaining 15 dewars, a further five discrepancies were recorded (errors the same as quoted above). These errors were rectified at the time. These issues were raised by the inspectorate with the Consultant Embryologist. She reported that this issue had been discussed within the team and was currently being addressed.
Summary of spot check of stored material
One patient's sperm samples (chemotherapy patient) were tracked from records to tanks. It was noted that there were no discrepancies found and samples had been split between two dewars in accordance with recommendations. One patient's embryos were tracked from notes to dewar. No discrepancies found. One patient's embryos were tracked from dewar to notes. No discrepancies were found.

Areas of firm compliance
Patients are assessed as per the unit's clinical protocols which were considered fit for purpose by the inspectorate, along with information gathered during consultation, past medical history obtained from GP or consultant referral and in line with the eligibility and availability of treatment requirements as set out by the PCTs. Patients have not been routinely been screened for HIV, Hepatitis B or Hepatitis C, although patients are recommended to have the tests in the patient information provided for their treatment. The PR and Service Manager reported during interview that screening for these conditions will be routinely performed on patients from April 2007. Donors are assessed as per the unit clinical protocols and are screened in accordance with best practice. Laboratory protocols are in place and considered fit for purpose by the inspectorate for the safe handling of patients' samples. The three embryo transfer log was inspected and shows that all patients receiving three embryos had been treated appropriately. Both the laboratory and main treatment room have been tested for their air quality. Results show that the cabinets are performing to Grade A air quality whilst background air measurements in both areas fall between Grade C and Grade D. This is accordance with the requirements set out in the EUTD Regulations. All laboratory witnessing steps were seen to be being carried out in accordance with witnessing regulations. It was also evidenced that all witnessing steps were adequately recorded within the laboratory documentation. Clinical ICSI data provided prior to the inspection showed good results for all ICSI practitioners. Protocols are in place which were considered fit for purpose by the inspectorate for the safe keeping and disposal of embryos and gametes. Trust protocols for the recruitment of staff are followed. It was noted that senior staff from the unit have active involvement in the recruitment process. It was noted that this process includes the verification of qualifications and registrations with professional bodies, performing a Criminal Records Bureau (CRB) assessment, and obtain all relevant references. On successful appointment, all new staff receives a general Trust induction. Evidence was provided to the inspectorate of a completed induction checklist for an embryologist and an induction programme for one of the medical consultants. All medical, nursing and scientific staff interviewed reported that they were provided sufficient opportunities and funding for their individual CPD requirements. Staff on the unit are also assessed on an ongoing basis against the Knowledge and Skills Framework model advocated by the Trust. Meetings are held every Monday evening, where all staff are encouraged to attend. During

these meetings, issues are discussed such as new protocols being introduced, updates on treatment protocols, discussion of potentially difficult cases and any issues regarding the general day to day running of the unit. Evidence of these meetings was provided to the inspectorate in the form of minutes. These minutes are circulated to all staff unable to attend.

Every Tuesday afternoon the centre holds educational meetings where various different topics are discussed. All staff are invited to these sessions. Staff interviewed on the day stated that these meetings are highly informative and helpful.

The staff have developed a thorough EUTD action plan and timetable which they are working against to ensure compliance with the EUTD Regulations.

Areas for improvement

It was noted that embryologists often perform the top up of dewars with liquid nitrogen, alone. For health and safety reasons, it was recommended that this operation be performed by at least two people. It was further reported that none of the embryology staff have to date received manual handling training. It was recommended that all embryology staff attend a manual handling course as a matter of some urgency, especially because of the decanting process required from one tank to another to top-up the dewars with liquid nitrogen.

It was noted that although all staff receive a general Trust induction upon successful employment, a general clinic induction is not provided to all staff. It was recommended that a general clinic induction programme should be developed for all new staff appointed to the unit.

Training logs are not maintained by all staff working within the centre. It was recommended that all staff (including administrative staff) monitor and log the training they undertake during their employment. This should include a “sign off” section when a new skill is learned showing that the member of staff has been considered competent to perform that skill.

Carbon dioxide tanks have been locked in a small storage area in the corridor outside the embryology laboratory since an incident was recorded at the centre where someone turned the tanks off. Plans are in place to move the tanks completely to a secure storage location outside of the building and then the gasses will be pumped into the laboratory from the outside. Although it was noted that these tanks are checked on a regular basis, it was recommended that the embryology staff check the tanks daily to ensure both sufficient supplies of the gas are available and that the switch over unit is working properly. This was agreed with the Consultant Embryologist.

During the course of the inspection of the laboratory, it was noted that both samples of sperm and embryos were stored in the same dry shipper. It was noted that this is not best practice and that embryos and sperm samples should be stored separately. The Consultant Embryologist agreed to modify this practice.

In the interests of health and safety, all staff accessing and using liquid nitrogen, should wear safety goggles.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection
PGD/PGS services are not currently offered at the centre.

Evaluation
Some improvement required

Report compiled by:

Name TONY KNOX

Designation Lead Inspector

Date 14th February 2007

Appendix A: Centre Staff interviewed

PR – Mr John Parsons
Seven other centre staff.

Appendix B: Licence history for previous 3 years

L0109/9/c

No conditions, no recommendations

L0109/9/b

Conditions

- The Person Responsible is reminded of his duty under Section 17 of the HF&E Act 1990 to ensure suitable practices are used in the course of activities, therefore the Person Responsible should ensure that all members of staff follow Health & Safety Regulations in that the practice of month pipetting in the laboratory should cease immediately.

No recommendations

L0109/9/a

Condition

- The Person Responsible is reminded of his duty under Section 17 of the HF&E Act 1990 to ensure suitable practices are used in the course of activities, therefore the Person Responsible should ensure that all members of staff follow Health & Safety Regulations in that the practice of month pipetting in the laboratory should cease immediately

Recommendations

- The Person Responsible should ensure all staff who have access to confidential patient information are included on the centre's licence, including staff who work at the centre occasionally.
- The centre's price list should be kept up to date if it is included in the patient information.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……

Date of Inspection……..

Date of Response…….

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

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

Signed……

Name……

Date……

2. 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).

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

Interim Inspection Report

ACU Kings College Hospital
0109

Date of Inspection: 13th February 2007
Date of Licence Committee: 23rd May 2007

TRIM: 06/5619

CENTRE DETAILS

Centre Address	1st Floor Mapother House Kings College Hospital Denmark Hill London SE5 9RS
Telephone Number	0207-346-5390
Type of Inspection	Interim Inspection
Person Responsible	Mr John Parsons
Nominal Licensee	Catherine Warwick
Licence Number	L0109/10/a
Inspector(s)	Tony Knox (Lead Inspector)
	Brian Woodward
	Tahir Hussain
Fee Paid - date	Not Due
Licence expiry date	30th September 2008

Index

Page

About the Inspection:
This inspection visit was carried out on 13th February 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between January and December 2006.

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 interim 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, recommendations 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.

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 centre is part of the Kings College Hospital NHS Trust and provides NHS and self funded treatments to patients primarily from the South East of England. The centre has provided DI treatment since 1975 and IVF treatment since 1983. The PR estimated that approximately 50% of the patients treated are funded by the local Primary Care Trusts (PCTs) of Lambeth, Lewisham, Southwark, Greenwich, Bexley and Barnet.

The centre provides no satellite services. However it does provide transport service arrangements with St. Hellier Hospital in Surrey.

Activities of the Centre

Figures given below are taken from HFEA data between January 2005 and December 2005

Licensed treatment cycles	IVF ICSI FET Egg donation Egg recipient	259 335 39 11 8
Donor Insemination		122
Unlicensed treatments	IUI Ovulation Induction with IUI Surrogacy	
Research	None	
Storage	YES	

Summary for Licence Committee

The centre was seen to be well organised and staffed appropriately for the level of activity currently undertaken at the unit. There is a good history at the centre of Regulatory compliance, and the staff have developed a detailed program of activity to ensure compliance with the EU Tissue and Cells Directive.

The inspectorate recommends the continuance of the centre's license without additional conditions being imposed.

Risk Assessment

The centre had been awarded a risk score of 21% pre-inspection. The risk score following this inspection was recorded at 16%

The unit follows the Trust policies and procedures for risk management, and since the time of the last inspection, fire and clinical incidents had been risk assessed by the unit staff.

The Service Manager has been approved to attend a five day health and safety course later in the year, after which additional focus will be given to conducting further risk assessments.

A detailed self assessment document was forwarded to the HFEA prior to the inspection. The assessment made by the inspectorate during the inspection finds that this is consistent with the findings in the self assessment document.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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 or Code of Practice

Breach	Action required	Time scale
None		

Non-Compliance

Area for improvement	Action required	Time scale
Producing room for patients referred by their GP was considered unfit for purpose by the inspectorate.	Improve the standards of the producing room.	As soon as possible

Recommendations	Time scale
Pulse oximeters are recommended for the two recovery bays to provide additional monitoring for patients recovering from sedation.	Immediate
Ensure that the practice of laboratory staff “topping up the dewars” is not performed as a solo activity.	Immediate
Monitor and check Carbon Dioxide CO_2 gas cylinders daily.	Immediate
Ensure that sperm samples and embryos are not stored together in the same dry shipper.	Immediate
Staff accessing and using liquid nitrogen should wear safety goggles in the interests of health and safety.	Immediate
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.	By end April 2007 and ongoing.
Formalise the centre’s contingency plan by producing a documented service level agreement.	As soon as possible
Produce a formally documented service level agreement between the centre and the transport unit.	As soon as possible
Devise an alternative means of notifying staff of patient arrival at the centre other than the use of the whiteboard system.	As soon as possible

Devise an alternative system for GP referred patients attending for semen assessment to leave their samples rather than walking through the unit.	As soon as possible
Ensure all laboratory staff attend a manual handling training course.	As soon as possible
Document a centre specific induction program for new starters.	As soon as possible
Introduce training folders for all centre staff. This should include evidence of competency "sign off".	As soon as possible

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
None	

Additional licence conditions and actions taken by centre since last inspection

C	**None**
A	**Complied Y/N**

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
All staff interviewed during the inspection stated that they were happy with the support received from senior management at the centre. There is a clear organisation structure of which all staff are aware. All staff interviewed stated that there were sufficient numbers of staff employed to manage the current activities of the unit. The centre follows the Trust policies for clinical governance and clinical risk. A Clinical Governance and Risk Committee has been set up for the hospital which meets monthly. Minutes from the meetings are taken and distributed throughout the hospital. Evidence of these minutes was seen during the inspection. The PR reports all incidents in accordance with the requirements of the HFEA. The incident policy is clear and all staff interviewed were aware of the process for reporting. A detailed action plan for the implementation of the European Union Tissues and Cells Directive (EUTD) requirements was provided to the inspectorate, and there was evidence provided to show that this is being followed. Work has commenced to introduce a quality management system to the centre. The Service Manager stated that a Quality Manager has been temporarily appointed to assist with this until April 2007, after which, budget has been approved to hire a specific Quality Manager/Nurse. Payments are made on time to the HFEA Finance Department.
Areas for improvement
The PR stated that there is as yet no formal documented contingency plan in place for the unit. However, there is verbal agreement that should the situation occur, patients whose treatment could not be safely stopped would be transferred to Guys Hospital fertility unit. It was agreed by the PR that a formal service level agreement (SLA) should be documented to

reflect this.

The centre provides Transport service arrangements for the St. Hellier Hospital, Carshalton, Surrey. It was noted that no formal SLA was in place for the provision of these services. It was agreed by the PR that this should be formerly documented.

A recommendation was made for the evening Monday meetings to be brought forward in the day (possibly lunchtime) which may improve staff attendance from all areas of the Clinic.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
Graphs produced from data provided to the HFEA prior to the inspection show that success rates for IVF and ICSI in most age groups were below the national average. The same is reflected in age group 40 to 42 for frozen embryo replacement. Success rates for donor insemination were above the national average, and ovarian hyper-stimulation syndrome (OHSS) rates were statistically insignificant. It was noted that these statistics were obtained from figures held on the HFEA register for the period 31st March 2002 and 1st April 2005. This was discussed with the PR. He reported that for a period of time, there had been no lead embryologist within the unit. This was rectified in 2005 with the arrival of the current head of embryology. In addition, he reported that for a six week period between March and May 2006, success rates were exceptionally poor. Despite a series of audits being performed at the time to isolate the reason for this, none had been discovered. It was reported that during the same period of time, laboratory desking had had to be cut to accommodate a new Class II hood. It was stated that these changes may have adversely affected the atmosphere within the laboratory and therefore impacted upon success rates although this could not be proven. In addition, all core staff within the unit changed between 2004 and the end of 2005 as rumours were circulating that the unit may have to close. Since the arrival of the lead embryologist, success rates have been steadily improving. Figures presented to the scientific inspector show that current success rates for all areas are now above the national averages. This will not be reflected however in the HFEA data due to the reported timescales.
Areas of firm compliance
Evidence was seen in the patients' notes that appropriate 'Welfare of the Child' assessments had been conducted. The patients' notes are housed in the area behind the main reception desk where the unit administration and secretariat work. Although it was noted that the filing cabinets used to house the notes were not locked, the area itself is secured by a locked door at the one end and by a roll down security tambour (which is also locked at night) by the

reception desk itself. This area is independently alarmed and linked to the main alarm system. This was considered suitable by the inspectorate.

Patients are assessed using the centres own protocols, which were considered fit for purpose by the inspectorate, and in accordance with funding guidelines from the various PCTs.

Any potentially difficult patient cases are discussed primarily at a multi-disciplinary team meeting. Where general consensus cannot be reached, these cases are referred to an Ethics Committee. Minutes taken at these meetings were evidenced.

The complaint policy provided to the inspectorate is clearly written and all staff interviewed were aware of the process required for reporting complaints. Three complaints have been received since the last inspection and all have been dealt with appropriately. A verbal complaints policy is also in operation.

A centre specific patient questionnaire has been devised and is in use within the unit. An audit of the completed questionnaires (36 responses from September to November 2006) had been compiled and was evidenced by the inspectorate during the visit. During her interview, the Service Manager reported that comments made in the questionnaires concerning improvements that could be made are discussed and where possible, improvement actions are taken.

Counselling is independent and provided free of charge to patients. The facilities used for counselling were evidenced and were considered to be fit for purpose by the inspectorate.

All donors are assessed and screened in accordance with the unit's policies and procedures which were considered fit for purpose by the inspectorate. Donor sperm is occasionally imported for use with named patients. All imports have been documented and actioned appropriately.

Areas for improvement

After registering attendance at the main reception, patients walk around the corridor (used as the centres waiting area) to a whiteboard where all patients' names are written for that day. Patients tick off their name on this board and then wait to be called. Whilst it was understood that this system provides benefits for the staff in knowing which patients' have arrived, its location in the corridor (within the unit), also shows other patients who is attending for treatment. This is considered to be a risk to confidentiality. This is further highlighted in the fact that male patients referred by their GP's for semen analysis only, have to pass the board in order to leave their specimens at the embryology laboratory for testing. Despite the PR noting that this had never been raised as an issue by patients in the past, it was recorded that this constitutes a breach of confidentiality and an alternative, less public system be introduced for staff.

Executive recommendations for Licence Committee

Recommendation to amend practice of displaying patient names in corridor to further protect patient confidentiality.

Areas not covered on this inspection
Egg sharing and surrogacy Protection of children arrangements

Evaluation
Some improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The unit was well signposted. The unit is housed within Mapother House, a separate building to the main hospital, and is shared by other medical disciplines. The door to the unit is locked and alarmed ensuring the security of the centre out of hours. A complaints poster, the centres licence, counselling poster, advertisement for the open evenings held and a patient questionnaire box were seen in the reception area of the unit. The reception desk allows the receptionist clear view of everyone entering the unit. Administration, secretaries and the receptionist work in this area, which also houses the patients' notes. These are stored in filing cabinets. There have been no changes to the premises since the last inspection, and all areas (with the exception of an additional room, just outside the unit, used as a male producing room for GP referred patients requiring only a semen analysis to be performed), were considered fit for purpose by the inspectorate. Storage dewars are housed within the embryology laboratory. All dewars were appropriately alarmed with access into the laboratory secured by both key lock and a digital key pad lock. A low oxygen alarm was also seen to be in place. There is a back-up generator in place which is tested weekly by the hospital maintenance department. A service log is kept showing when maintenance of all critical equipment is performed which was evidenced during the inspection. Incidents are reported in accordance with both HFEA requirements and the units own protocols. Between the last inspection and this inspection, the centre has reported ten incidents, all of which have been appropriately dealt with and have been "closed" by the HFEA. An emergency trolley was situated in the corridor outside the main treatment room where egg collections, replacements and IUIs are performed. It was evidenced that this had been checked daily. Although a defibrillator was not available on the unit, centre staff advised that one was located on the ward below the unit and would be used if required. Evidence was seen that portable appliance testing of equipment had been performed in December 2006.
Areas for improvement
A separate producing room to the one used by fertility patients is provided for patients attending the unit for semen analysis only. These patients are referred from their GP surgery.

The producing room is just outside the doors to the main unit. This was considered by both the inspectorate and the unit staff to be unsuitable. In addition, after producing a sample in this area, the patient transports the sample into the unit, reports to the reception desk and is then directed around the corridor (used as a waiting area for the fertility unit patients) to deposit the sample at the embryology laboratory. Centre staff were advised to devise an alternative system preventing access to the remainder of the fertility unit to these patients.

Following egg collection procedures, patients are moved to one of two recovery rooms across the corridor from the main treatment room. Although a nurse call bell system is in operation within both rooms, it is recommended that additional pulse oximeters be purchased to monitor patients recovering from their sedation.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered

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:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Sixteen sets of patient records were checked during the inspection. Seven sets of records were noted as containing errors relating primarily to incomplete consent forms and incomplete witnessing checklists. (It was noted by the scientific inspector that all witnessing records maintained in the laboratory were complete and in accordance with witnessing directions). It was noted by the Service Manager that an audit of patient notes for consents had been initiated and was currently ongoing. Errors found were being rectified with the patients.
Areas of firm compliance
The staff use the IDS patient database to store patient treatment information. Use of the system is restricted to authorised personnel only, with each member of staff being allocated a password. A backup is taken of the information each evening which is then stored securely. HFEA Registry Department reported no problems with data submission and updates. A small filing cabinet is used to hold all current patient information and treatment/consent forms which is maintained by the Service Manager and Quality Manager. Staff only use forms from this filing system to give to patients. Following a change to any of the documentation, the Service Manager or Quality Manager ensure that the old documentation is removed and replaced with the new. This ensures that only up to date documentation is used.
Areas for improvement
A large number of policies and procedures were submitted for review prior to the inspection. Whilst the majority of these were considered fit for purpose by the inspectorate, a number of inconsistencies were also noted. Examples of these inconsistencies included the “Clinical Protocol for IVF and ET”, where both the old 006 and 007 consent forms and new MT and WT consent forms are given to patients to complete. These were brought to the attention of the PR during the interview who reported that these would be changed. The policies and procedures submitted for review were seen as being in different formats. It was explained by the Service Manager that all policies and procedures (approximately 500) are in the process of being reviewed and amended to be on a standard template. It was further reported that the new documents will be version controlled and dated. The Service Manager estimated that this project will be completed by April 2007.

Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

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:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3 x Consultant Grade 2 x Specialist Registrar positions 2 x Clinical Fellows
NMC registered nurses	7
HPC registered scientists	1
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	8 (1 x Service Manager, 1 x administrator, 3 x secretaries, 2 x receptionists and 1 x independent counsellor).

Summary of laboratory audit
An audit of all dewars was conducted between 12th and 13th December 2006. An undisclosed number of errors were reported from the three dewars used to store donor sperm. Some samples had been transferred from the quarantine tank to the cleared dewars without amending the file system. These errors were rectified. Of the remaining 15 dewars, a further five discrepancies were recorded (errors the same as quoted above). These errors were rectified at the time. These issues were raised by the inspectorate with the Consultant Embryologist. She reported that this issue had been discussed within the team and was currently being addressed.
Summary of spot check of stored material
One patient's sperm samples (chemotherapy patient) were tracked from records to tanks. It was noted that there were no discrepancies found and samples had been split between two dewars in accordance with recommendations. One patient's embryos were tracked from notes to dewar. No discrepancies found. One patient's embryos were tracked from dewar to notes. No discrepancies were found.

Areas of firm compliance
Patients are assessed as per the unit's clinical protocols which were considered fit for purpose by the inspectorate, along with information gathered during consultation, past medical history obtained from GP or consultant referral and in line with the eligibility and availability of treatment requirements as set out by the PCTs. Patients have not been routinely been screened for HIV, Hepatitis B or Hepatitis C, although patients are recommended to have the tests in the patient information provided for their treatment. The PR and Service Manager reported during interview that screening for these conditions will be routinely performed on patients from April 2007. Donors are assessed as per the unit clinical protocols and are screened in accordance with best practice. Laboratory protocols are in place and considered fit for purpose by the inspectorate for the safe handling of patients' samples. The three embryo transfer log was inspected and shows that all patients receiving three embryos had been treated appropriately. Both the laboratory and main treatment room have been tested for their air quality. Results show that the cabinets are performing to Grade A air quality whilst background air measurements in both areas fall between Grade C and Grade D. This is accordance with the requirements set out in the EUTD Regulations. All laboratory witnessing steps were seen to be being carried out in accordance with witnessing regulations. It was also evidenced that all witnessing steps were adequately recorded within the laboratory documentation. Clinical ICSI data provided prior to the inspection showed good results for all ICSI practitioners. Protocols are in place which were considered fit for purpose by the inspectorate for the safe keeping and disposal of embryos and gametes. Trust protocols for the recruitment of staff are followed. It was noted that senior staff from the unit have active involvement in the recruitment process. It was noted that this process includes the verification of qualifications and registrations with professional bodies, performing a Criminal Records Bureau (CRB) assessment, and obtain all relevant references. On successful appointment, all new staff receives a general Trust induction. Evidence was provided to the inspectorate of a completed induction checklist for an embryologist and an induction programme for one of the medical consultants. All medical, nursing and scientific staff interviewed reported that they were provided sufficient opportunities and funding for their individual CPD requirements. Staff on the unit are also assessed on an ongoing basis against the Knowledge and Skills Framework model advocated by the Trust. Meetings are held every Monday evening, where all staff are encouraged to attend. During

these meetings, issues are discussed such as new protocols being introduced, updates on treatment protocols, discussion of potentially difficult cases and any issues regarding the general day to day running of the unit. Evidence of these meetings was provided to the inspectorate in the form of minutes. These minutes are circulated to all staff unable to attend.

Every Tuesday afternoon the centre holds educational meetings where various different topics are discussed. All staff are invited to these sessions. Staff interviewed on the day stated that these meetings are highly informative and helpful.

The staff have developed a thorough EUTD action plan and timetable which they are working against to ensure compliance with the EUTD Regulations.

Areas for improvement

It was noted that embryologists often perform the top up of dewars with liquid nitrogen, alone. For health and safety reasons, it was recommended that this operation be performed by at least two people. It was further reported that none of the embryology staff have to date received manual handling training. It was recommended that all embryology staff attend a manual handling course as a matter of some urgency, especially because of the decanting process required from one tank to another to top-up the dewars with liquid nitrogen.

It was noted that although all staff receive a general Trust induction upon successful employment, a general clinic induction is not provided to all staff. It was recommended that a general clinic induction programme should be developed for all new staff appointed to the unit.

Training logs are not maintained by all staff working within the centre. It was recommended that all staff (including administrative staff) monitor and log the training they undertake during their employment. This should include a “sign off” section when a new skill is learned showing that the member of staff has been considered competent to perform that skill.

Carbon dioxide tanks have been locked in a small storage area in the corridor outside the embryology laboratory since an incident was recorded at the centre where someone turned the tanks off. Plans are in place to move the tanks completely to a secure storage location outside of the building and then the gasses will be pumped into the laboratory from the outside. Although it was noted that these tanks are checked on a regular basis, it was recommended that the embryology staff check the tanks daily to ensure both sufficient supplies of the gas are available and that the switch over unit is working properly. This was agreed with the Consultant Embryologist.

During the course of the inspection of the laboratory, it was noted that both samples of sperm and embryos were stored in the same dry shipper. It was noted that this is not best practice and that embryos and sperm samples should be stored separately. The Consultant Embryologist agreed to modify this practice.

In the interests of health and safety, all staff accessing and using liquid nitrogen, should wear safety goggles.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection
PGD/PGS services are not currently offered at the centre.

Evaluation
Some improvement required

Report compiled by:

Name TONY KNOX

Designation Lead Inspector

Date 14th February 2007

Appendix A: Centre Staff interviewed

PR – Mr John Parsons
Seven other centre staff.

Appendix B: Licence history for previous 3 years

L0109/9/c

No conditions, no recommendations

L0109/9/b

Conditions

- The Person Responsible is reminded of his duty under Section 17 of the HF&E Act 1990 to ensure suitable practices are used in the course of activities, therefore the Person Responsible should ensure that all members of staff follow Health & Safety Regulations in that the practice of month pipetting in the laboratory should cease immediately.

No recommendations

L0109/9/a

Condition

- The Person Responsible is reminded of his duty under Section 17 of the HF&E Act 1990 to ensure suitable practices are used in the course of activities, therefore the Person Responsible should ensure that all members of staff follow Health & Safety Regulations in that the practice of month pipetting in the laboratory should cease immediately

Recommendations

- The Person Responsible should ensure all staff who have access to confidential patient information are included on the centre's licence, including staff who work at the centre occasionally.
- The centre's price list should be kept up to date if it is included in the patient information.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR……

Date of Inspection……..

Date of Response…….

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

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

Signed……

Name……

Date……

2. 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).

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