Licence Renewal Inspection Report for Treatment and Storage Centres

Sussex Downs Fertility Centre
0015

Date of Inspection: 6th December 2006
Date of Licence Committee: 21st March 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Esperance Private Hospital ACU Hartington Place Eastbourne East Sussex BN21 3BG
Telephone Number	01323-410333
Type of Inspection	Renewal
Person Responsible	Mr David Chui
Nominal Licensee	Mrs Susan Mulvey
Licence Number	L0015/13/a
Inspector(s)	Tony Knox (Lead) Sarah Hopper Parvez Qureshi
Fee Paid - date	
Licence expiry date	30th June 2007

Index

About the Inspection:
This inspection visit was carried out on 6th December 2006 and lasted for 7.5 hours. The report covers the pre-inspection analysis, the visit and information received between 26th January 2006 and 31st 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 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, 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 was first established in 1991 and offers a wide range of licensed treatment services. It is housed within the BMI Esperance Hospital in Eastbourne. It treats privately funded patients from the surrounding population in East Sussex (Hastings and Haywards Health) and West Sussex (Brighton and Worthing) and 250 NHS funded treatments to the Adur, Arun and Worthing Teaching PCT through a contract awarded to the centre since the last inspection. It was estimated that the split between private and NHS funded patients is 50/50. Patients are generally referred by their GP.

The unit is open six days per week 8.30 – 16.30 Monday to Friday and 9.00 – 12.00pm Saturdays. Egg collections are performed mainly on Monday and Tuesday, although some are performed on Thursdays and Saturdays when required.

The unit, which is well signposted within the hospital, consists of a counselling room, treatment room (IUI and delivering drug administration training to patients), main office used by nurse co-ordinators and administrators, consulting room, patient waiting room (licence, counselling information, complaints procedure and fees displayed), office for the ACU manager, locked drug store and male producing room. These areas are all located on the third floor of the hospital and were considered fit for purpose. The operating theatre, embryology laboratory, cryostore and three-bay recovery area are all located in the lower ground floor of the hospital. All procedures conducted within the operating theatre are performed in the presence of a consultant anaesthetist, who can offer a choice of either sedation of general anaesthetic.

Since the last interim inspection the centre received an unannounced inspection visit by Tony Knox and Marion Witton. No problems were recorded at that visit. At that visit, the staff at the unit explained that they were in the process of preparing a "stand" at the forthcoming "Brighton Gay Pride" where it was their intention to recruit sperm donors. The staff were contacted following the event where they reported some success in this venture.

Since the last inspection, the centre has been awarded ISO certification.

The last Healthcare Commission inspection was conducted on 19th November 2006. No recommendations for improvement were made.

Activities of the Centre

Figures supplied for 1/1/05 – 31/12/05

Licensed treatment cycles	IVF ICSI FET	68 39 5
Donor Insemination		53
Unlicensed treatments	IUI	
Research	N/A	0
Storage	YES	

Summary for Licence Committee

The inspection team recommend renewal of the centres treatment licence for a period of three years.

Risk Assessment

Prior to this inspection, the centre was assessed as having an 11% risk rating. Following the inspection, the risk rating for the centre was 5%.

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
Witnessing steps were not always recorded in accordance with Directions 2004/4 Chairs letter 04/02. This includes an additional recorded witnessing step being required from checking sperm gradient to first wash at the time it is performed.	All witnessing steps to be documented and include a date, time and signature.	Immediate

Non-Compliance

Area for improvement	Action required	Time scale
Patient and donor information relating to sperm donor treatments does not currently reflect changes made by the SEED Regulations.	All patient and donor information to be updated to reflect the change from 10 live birth event to 10 family events.	Immediate.

Recommendations	Time scale
A formal contingency Service Level Agreement (SLA) must be documented to ensure continuance of service for patients should treatment services at the centre be suspended for any reason.	Three months
Activity levels within the unit to monitored, and staffing of the unit to be adjusted as necessary to cope with any increase in treatment cycles performed.	Ongoing
Complaints log to be modified to contain a more detailed account of how complaints are handled.	Immediate.
Consideration should be given to employing a second counsellor to act as backup for the existing counsellor. Again, this should take particular account of increased numbers of patients being treated within the centre.	Immediate.
Door to the cryostore to be kept locked at all times when not in use.	Immediate.
Consideration be given to introduce a system to record all treatment service provision. This system to be used alongside the current paper based system which can be backed up and recovered in the event of destruction of paper records.	Immediate.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Witnessing procedures at weekends were not always being performed contemporaneously.	All witnessing steps are now performed at the time of the procedure as evidenced in the notes.
Ambiguity existed within the witnessing policy regarding the stages where witnessing was required.	Witnessing policy clarified and submitted pre-inspection. This was evidenced and was considered fit for purpose by the last inspectorate.
Inaccuracies were noted in a number of patient records audited at the last inspection concerning consent forms.	An ongoing program of monthly patient notes audit is performed by both embryology and nursing staff to ensure that all records contain accurate information and appropriate consents.

Additional licence conditions and actions taken by centre since last inspection

C	NONE

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
There is a clear organisation structure within the unit as evidenced through the organogram provided pre-inspection and confirmed during interview with various members of staff. Levels of authority were clearly defined. All staff interviewed stated that there are sufficient numbers of staff within the unit to manage the current throughput of patients and treatment cycles. BMI recruitment policies are followed which enable key members of staff from the unit to have active involvement in recruiting staff for their own unit. These policies also ensure that all staff are appropriately qualified prior to an appointment being offered. All staff interviewed were aware of the incident reporting process. Since the last inspection, two further incidents have been reported to the HFEA. These were graded as low risk and have been subsequently closed. Prior to tendering for the NHS contract, full consideration was given by key personnel within the unit to ensure that staffing levels, equipment and the premises were sufficient to ensure the additional treatment cycles could be accommodated within the unit. According to the Finance Department at the HFEA, all treatment fees are up to date and regular payments are made. Since the last inspection, a system of conducting monthly audits of all patient notes has been introduced along with reconciliation of samples stored within the laboratory. These audits are conducted with the involvement of both embryology and nursing staff.
Areas for improvement
Whilst staffing levels within the unit are currently acceptable for its current activity, it was reported by the PR and ACU Manager that the BMI Healthcare has been approached for additional funding for a healthcare assistant and additional administration hours in anticipation of further increased level of activity relating to the NHS contract awarded this year. It was

agreed with the PR and ACU Manager that any further increases in the numbers of patients currently treatment may necessitate additional nursing and embryology staff and as such, the numbers of cycles conducted at the centre should be closely monitored.

HFEA alerts received by the centre are distributed only to whom the alert has direct relevance. Consequently, nursing staff were unaware of the last HFEA alert as it pertained mainly to laboratory practice. It was recommended that the PR introduce a system to ensure all staff are made aware of all HFEA alerts.

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

- 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

Live birth data obtained from the HFEA covers the period of 31st March 2002 to 1st April 2005. This information shows IVF/ICSI rates for age groups 40-42 and < 35 to be below the national averages. FET rates for age groups 38-42 to also be below the national averages. These figures were discussed with the PR and the ACU Manager. It was noted that between 2002 and 2004, success rates had been poor. However, since that time, success rates had improved. This is not reflected in the HFEA data as the data presented is cumulative.

Data provided by the centre on the day of inspection showed outcomes from treatments provided during 2005. The figures given below are the ongoing/live birth rates for both IVF and ICSI: -

IVF Outcomes 2005

Age Group	Cases	Abandoned	ET	Ongoing/LB
≥ 30	6	0	6	3 = 50%
31-35	23	1	22	8 = 36.4%
36-39	26	1	25	9 = 36.0%
≥ 40	13	2	11	1 = 9.1%
TOTALS				
	68	4	64	21 = 32.8%

ICSI Outcomes 2005

Age Group	Cases	Abandoned	ET	Ongoing/LB
≥ 30	5	0	5	0
31-35	17	1	16	6 = 37.5%
36-39	9	1	8	3 = 75%
≥ 40	8	4	4	3 = 75%
TOTALS				
	39	6	33	12 = 36.4%

Combined conventional IVF and IVF with ICSI Outcomes 2005

Age Group	Cases	Abandoned	ET	Ongoing/LB
≥ 30	11	0	11	3 = 27.3%
31-35	40	2	38	14 = 36.8%
36-39	35	2	33	12 = 36.4%
≥ 40	21	6	15	4 = 26.7%
TOTALS				
	107	10	97	33 = 34.0%
Under 40	86	4	82	29 = 35.4%

OHSS rate taken from the HFEA data shows a 0.64% rate which is below the national average.

Areas of firm compliance

Welfare of the Child (WOC) assessments were evident in all notes audited during the inspection. Any potentially contentious cases are discussed in the regular multidisciplinary meetings with all staff (evidenced in the unit meeting minutes) for a general consensus as to whether to offer treatment or not. Where agreement cannot be reached, cases are forwarded for discussion at the next Ethics Committee meeting. (Minutes evidenced). Where a decision is made not to treat, the patients are brought back to the unit and the reasons for the refusal to treat are explained by the PR. The PR stated that this is then documented in the patients' notes.

All patient notes are kept in locked storage cabinets in the locked main office. All staff interviewed were aware of the requirement for confidentiality.

Written patient information contains a full explanation of all treatments available at the unit. Patients interviewed stated that if they were unsure of any aspect of their treatment they would have no hesitation in contacting the centre where they could discuss their treatment with the most appropriate member of staff. The patients interviewed stated that privacy and dignity were maintained at all times, and they expressed their complete satisfaction with the treatments they were having.

Since the last inspection three additional patient questionnaires have been received at the HFEA. All responses received reflect positively on the premises, staffing and level of care they have received at the unit. In addition, the centre also conducts its own patient satisfaction surveys through the BMI Group questionnaire. Responses received are collated and a report issued to staff within the unit. These were evidenced during the inspection and showed very positive feedback from the patients. Staff interviewed stated that they are made aware of the results of these reports during the regular multidisciplinary meetings.

The counselling facilities were inspected and considered by the inspectorate to be fit for purpose. The last counselling audit completed was for the period 1/9/05 to 31/8/06. This shows that 58 implications counselling sessions had been conducted of which 31 sessions were for sperm recipients. There had been a further 57 therapeutic counselling sessions conducted (27 sessions for IVF, 10 sessions for ICSI and a further 12 sessions for sperm recipients). Counselling is provided free of charge either within the unit or at the counsellors

home address in Brighton. All counselling records are held on computer which is password protected with access to the counsellor only.

Areas for improvement

Although there is a clear policy for the handling of complaints, the complaints file was incomplete. It was recommended that the complaints log contain copies of all correspondence between the centre and the complainant along with details of how the complaint was successfully resolved. This information is currently recorded only in the patients' notes. This was agreed by the PR.

Whilst sperm donors receive some implications counselling primarily regarding screening tests and the removal of anonymity from nursing and embryology staff, it was noted from the counselling audit that the independent counsellor had no recorded sessions with this group. On interview, the independent counsellor stated that this was not a function that she currently deals with, whilst interviews with the PR and ACU Manager recorded that this was a service provided by the counsellor should it be required. It was agreed by the PR and ACU Manager that this confusion would be corrected, and counselling would be provided by the independent counsellor (as evidenced in the sperm donor information), should it be requested.

The counsellor reported a rise in the number of counselling sessions performed over the past year, primarily due to the centre being awarded an NHS contract. Whilst the counsellor reported that she was able to accommodate these additional sessions, it was noted that she is the only independent counsellor for the unit. It was recommended to the PR and ACU Manager that an additional counsellor is recruited who would be able to "cover" for unexpected illness and holidays, and provide additional counselling sessions should the demand for counselling increase.

It was recommended that consideration be given to purchasing an IVF database for all information, currently recorded only in paper form. It was noted that this information could be then backed up at regular intervals providing additional security of information in the event of fire destroying all patient records and assist the centre in auditing their own results. It was agreed by the PR and the ACU Manager that funding for such a system would be applied for to the BMI Group for authorisation.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Egg sharing and surrogacy – no treatments provided.
Protection of children policy – currently no treatments provided to patients under the age of 18 as noted by the PR and ACU Manager.

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 inspectors considered that there is adequate space provided within the unit for the treatment of patients. All areas are clean and fit for purpose. There are 17 liquid phase storage dewars. These were found to be individually locked and appropriately alarmed. The alarms are all connected to an autodial facility. Low oxygen alarms are in place for both the embryology laboratory and the cryostore. Policies are in place to ensure that an on call member of staff can respond to an emergency should it arise. A copy of the on call rota was evidenced at the main switchboard. All equipment used is detailed on a maintenance schedule which was evidenced at the inspection. The schedule details the dates of the next service for the equipment. This was seen to be in date and all critical equipment covered.
Areas for improvement
Whilst a keypad security lock on the cryostore door was seen, at the time of the inspection, the door had been left open. It was agreed by the ACU Manager that this door should remain closed when not in use.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered
Evaluation
No 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
A total of 22 sets of patient notes were selected from the treatment cycles record book, all chosen from the time of the last inspection. Notes selected were taken from patients who had undergone a range of treatments from IVF, IVF with ICSI, donor insemination and frozen embryo transfer only. In one set of notes it was noted that a consent form HFEA 006 was missing. It was recorded in the front of the notes that this form had been removed and was located within the laboratory. Centre staff were advised that copies of all consent forms should be maintained in the notes. All other documentation within the notes were found to be included and satisfactory including consideration given to Welfare of the Child Assessment and consent to disclosure forms.
Areas of firm compliance
With only a few exceptions, detailed in this report, the information to patients is clear and explains medical terminology used in assisted reproductive treatments. This was evidenced in the information provided pre-inspection. Additional information requested on the day of the inspection was retrieved quickly and presented to the inspectors indicating a well organised information management system. The patient notes audited contained all relevant consent forms. This has been the result of the auditing system implemented following the last inspection. Most policies and protocols produced pre-inspection, plus additional procedures requested on the day, were detailed, complete and up to date. Some exceptions to this are highlighted in other areas of this report. The policies and procedures are held on a computer, accessible to staff in read only format. It was explained by the PR and the ACU Manager that these are reviewed annually by the most relevant member of staff and then changes are made to the master copy on the computer. Two folders containing all of the policies and procedures are also produced. These are located in the main office and the Embryology laboratory (evidenced). These are stamped to indicate that they are original copies. It is the responsibility of the ACU Manager to ensure that these folders are updated when a change is made to the computer copy of the policy. HFEA registry reported no problems from this centre pre-inspection, and stated that they were in receipt of regular updates via the EDI system.

Areas for improvement
Whilst policies and procedures for all areas of activity were clearly documented, comprehensive, contained name of person generating the policy and a date for revision, they were not version controlled. It was recommended that a version number be added to all policies. This was agreed by the PR and the ACU Manager. Information to patients and donors concerning donation and the use of donor sperm was not found to be in line with the "SEED" Regulations, as information currently provided makes reference to "10 Live Birth" events rather than 10 Family Events. In addition, it was recommended that clarification regarding counselling for those seeking treatment with donor gametes be clarified as the current information alludes to counselling being both mandatory and optional. The Counsellor, PR and ACU Manager confirmed that counselling for those requiring treatment with donor gametes was mandatory, and it was agreed that the information sheet would reflect this. Information provided to patients concerning the posthumous use of embryos provided information only for instances where the male partner died. It was recommended that this information be updated to include events where the female patient agrees to the posthumous use of her embryos in the event of her death. This should also include the requirement for additional screening. This was agreed with the PR and the ACU Manager.
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	2
NMC registered nurses	2
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	2

Summary of laboratory audit
Last reported laboratory audit was conducted for the period 23/11/2005 and 3/2/2006. Seventy three embryos were audited – no discrepancies were noted between their dewar location and the records. One error was noted on the patients' consent which was subsequently corrected by the patient. 386 sperm samples were audited – no discrepancies were found between the dewar location and the records. No discrepancies were found relating to the patient consents. The centre has a total of 17 liquid phase dewars, located either within the laboratory itself or within an adjacent cryostore. Both areas are accessible to authorised staff only and are secured by key pad locks.
Summary of spot check of stored material
An audit of two embryo samples from dewar to records and two samples from records to dewar was conducted during the inspection. No discrepancies were found. Two semen samples were audited from dewar to records and two samples from records to dewar. No discrepancies were found.
Areas of firm compliance
All staff working within the unit are suitably qualified to perform the duties they were employed to perform. All staff interviewed felt supported in their continuing professional development (CPD) and their ongoing mandatory training provided internally at the centre.

Policies, procedures and practice, clinical and scientific were generally seen to be robust and fit for purpose.

The staff work as a cohesive unit with all staff commenting on how supported they feel by both the management of the unit as well as their colleagues.

Staff interviewed were aware of the incident reporting procedure and the types of incidents which should be reported.

Areas for improvement
Whilst it was evidenced that witnessing standards were being practiced within the laboratory, further information in the documentation of these steps is required. It was also recommended that a modification to the laboratory witnessing form be made to record the step between sperm gradient measurement and the first sperm wash. This was agreed with the Senior Embryologist (ACU Manager). The PR was reminded that all witnessing steps must be documented as delineated in Directions D2004/4. During an interview with a member of the nursing staff she stated that in addition to attending external training in scanning, internal training and supervision had been provided by the PR in this function. She stated that the PR had assessed her as being competent to scan unsupervised. It was noted by the inspectors that there was no documented evidence in the nurses training record indicating this. It was recommended that all staff receiving internal training by suitably qualified and competent staff, should, on completion of their training, be "signed off" as competent with a copy of that record filed within their training log. This was agreed by the PR and ACU Manager.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
PGD and PGS are at performed at this centre.
Evaluation
Some improvements required.

Report compiled by:

Name: TONY KNOX

Designation: Lead Inspector

Date: 7th December 2006

Appendix A: Centre Staff interviewed

Person Responsible
ACU Manager (Senior Embryologist)
Independent Counsellor
4 Other Centre Staff
2 Patients

Appendix B: Licence history for previous 3 years

2006
Unannounced inspection visit 3rd August 2006
No problems identified.

Interim Inspection 26th January 2006
Licence Committee 24th May 2006
Licence Committee noted that because of inconsistencies found in consent forms during the inspection, the focus of the next inspection should be on the consent forms.
The Committee agreed that the centre's licence should continue with no additional conditions.

2005
Licence Committee 28th April 2005
The Committee agreed to renew the centre's licence for a period of two years

2004
Licence Committee 11th February 2004
The Committee agreed to suspend the centre's licence for a period of 3 months

2003
Licence Committee 14th August 2003
The Committee agreed to renew the centre's licence for nine months with four additional conditions: -

1.
The Person Responsible must ensure that the laboratory is equipped with a low oxygen-level alarm as a matter of health and safety. Furthermore he must ensure that the storage dewars in the same laboratory are fitted with low nitrogen-level alarms in order to fulfil obligations resulting from Parts 2.14, 10.1 & 10.5 of the Fifth Edition of the HFEA Code of Practice, and of Part 3 of the ACE Accreditation Standards and Guidelines for IVF Laboratories.
2.
The Person Responsible must ensure that the practice of mouth-pipetting within the centre is discontinued with immediate effect.
3.
The Person Responsible must ensure that the relevant clinical and laboratory protocols are amended to include appropriate witnessing steps or to refer to the centre's central witnessing protocol.
4.
The Person Responsible must ensure that the centre's welfare of the child protocol is amended to detail the steps that would be taken if the patient's GP refused to respond or raised concerns.

And 8 recommendations.

Licence Committee 8th May 2003
The Committee agreed to vary the centre's licence to recognise Mr David Chui as Person Responsible.

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

Sussex Downs Fertility Centre
Response and associated action plan for draft Inspection report
07.02.07

Key Points

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Witnessing steps were not always recorded in accordance with Directions 2004/4 Chairs letter 04/02. This includes an additional recorded witnessing step being required from checking sperm gradient to first wash at the time it is performed.	All witnessing steps to be documented and include a date, time and signature.	Immediate

Action

Laboratory sheets have been amended to ensure the step from gradient to wash tube is suitably witnessed. All staff have been advised that witnessing must now include date and time as well as signature.

Non-Compliance

Area for improvement	Action required	Time scale
Patient and donor information relating to sperm donor treatments does not currently reflect changes made by the SEED Regulations.	All patient and donor information to be updated to reflect the change from 10 live birth event to 10 family events.	Immediate.

Action

All relevant donor and patient information has been updated to reflect changes made by the SEED regulations and changed to reflect the change from 10 live birth events to 10 family events.

Recommendations	Time scale
1. A formal contingency Service Level Agreement (SLA) must be documented to ensure continuance of service for patients should treatment services at the centre be suspended for any reason.	Three months
2. Activity levels within the unit to monitored, and staffing of the unit to be adjusted as necessary to cope with any increase in treatment cycles performed.	Ongoing
3. Complaints log to be modified to contain a more detailed account of how complaints are handled.	Immediate.
4. Consideration should be given to employing a second counsellor to act as backup for the existing counsellor. Again, this should take particular account of increased numbers of patients being treated within the centre.	Immediate.
5. Door to the cryostore to be kept locked at all times when not in use.	Immediate.
6. Consideration be given to introduce a system to record all treatment service provision. This system to be used alongside the current paper based system which can be backed up and recovered in the event of destruction of paper records.	Immediate.

Actions

1. A detailed SLA with other BMI centres is being drawn up. Timescale for completion 31.03.07.
2. Activity levels are being consistently monitored. The Executive Director has been made aware that should levels significantly increase the Units staffing will need to be adjusted accordingly.
3. Complaints policy and procedure has been reviewed and expanded.
4. Investigations are underway to locate a suitable back up counsellor. The existing counsellor has suggested using the services of a student counsellor to support the counselling service currently offered at the SDFC. She believes this will be a good development and will supervise all the sessions the student undertakes (remote supervision). Alternatively the unit will enlist the support of an existing counsellor provided a suitable person can be found. A decision will be made on how best to proceed by 31.03.07
5. The door to the cryostore is routinely kept closed. It was an exception for it to be open on this particular day.
6. Investigations in to a suitable database have been ongoing. This report and associated

recommendation will be forwarded to the Executive Director for her consideration.

Additional actions and comments from rest of report

Organisation

- All HFEA alerts will be distributed to all staff – effective immediately

Quality of service

- There may have been some misunderstanding between the Counsellors comments and subsequent reporting. After discussion with Linda Greenaway and Mr David Chui she has stated that she actually said that she did not see sperm donors routinely, but was aware that her services are made available to them at the time of consultation

Premises and equipment

- No additional comments

Information

- All staff have been reminded that copies of consents should be maintained in both sets of notes when the male partner has a separate set to the female
- All policies and procedures will be versionised. Timescale by 30.05.07
- Information will be updated to include events where the female patient agrees to the post humous use of her embryos in the event of her death. Time scale for completion 31.03.07

Laboratory and Clinical Practice

- A sign off system has been implemented when staff receive in house training

(Comments received via E Mail and Copied into Report 12/12/2007)

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).

Summary states 'Some Improvements Required' however incorrect on report states 'No Improvements Required' for section Premises and Equipment.

(Comments received from the PR by Fax and copied into 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