Interim Inspection Report

Glasgow Royal Infirmary ACS
0037

Date of Inspection: 30th May 2007
Date of Licence Committee: 3rd September 2007

CENTRE DETAILS

Centre Address	Glasgow Royal Infirmary Assisted Conception Service Walton Building 84 Castle Street Glasgow G4 0SF Scotland
Telephone Number	0141-211-4428
Type of Inspection	Interim Inspection
Person Responsible	Mr Robin Yates
Nominal Licensee	Dr Helen Lyall
Licence Number	L0037-11-C
Inspector(s)	Tony Knox Sarah Hopper Grace Cunningham
Fee Paid - date	Not Due
Licence expiry date	31st December 2008

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About the Inspection:
This inspection visit was carried out on 30th May 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between July 2006 and June 2007.

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 was first licensed to carry out treatments in 1992, and has a good history of regulatory compliance.

The centre mainly treats NHS patients from the West of Scotland, having contracts with five of the surrounding health authorities. Patients are mainly referred to the centre by their GP, with some being referred through the university services. Treatment services are also provided to local asylum seekers and refugees, for whom they have access to interpreters if required. The PR stated that the estimated split between private and NHS funded patients is around 90% NHS funded and 10% private.

The centre is very busy and open seven days a week: - Monday to Friday 8am to 5pm, Saturday 8am to 2pm and Sunday 8am to 11am. Egg collections are not conducted on either Saturday or Sunday and embryo transfers are not conducted on Sundays.

The centre is split between two sites within the Glasgow Royal Infirmary. Consultations, scans and administration services are located within the Walton Building whilst the laboratory, treatment room, men's production room, waiting room, quiet room, four bedded recovery area, operating theatre and cryostores are located within the Queen Elizabeth Building.

There have been no further developments as yet with regards to locating the unit within a single site at the Glasgow Royal Infirmary although discussions regarding this are still being held.

Activities of the Centre

Data obtained from HFEA database 1/1/06 – 31/12/06

Licensed treatment cycles	IVF ICSI Egg Donation	167 125 7
Donor Insemination		11
Unlicensed treatments	IUI Ovulation Induction Surrogacy	
Research		Yes
Storage		Yes

Summary for Licence Committee

The centre appears well organised and many improvements have been made since the last inspection. The executive recommends continuance of the centres licence with no additional licence conditions.

Risk Assessment

Prior to the inspection, the centre had been awarded a risk score of 21%. Following the inspection, the risk score was again calculated and is now 16%.

On 14th May 2007, a Licence Committee considered the centre application to vary the centres licence for the EU Tissue and Cells Directive requirements. This was approved.

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
Policy for witnessing within the laboratory does not reflect changes in practice introduced since the previous inspection.	Policy to be updated to include all witnessing steps performed.	Immediate.
Women who attend for treatment and sign consent for their partners to use their embryos in the event of their death are not currently screened or registered as donors.	Women who sign consent to allow their partners to use their embryos in the event of their death should be screened and registered as donors.	Immediate.
Blood samples are currently tested within the university laboratories which do not meet with the requirements of being CPA accredited or accredited to an equivalent standard.	All blood tests must be conducted in a laboratory which meets CPA or equivalent standards.	Within six months.

Comment [C1]: See comments on 0115 report

Comment [C2]: This was not a reqitrement of the 6th Code of practice. I would highlight in the report that this will be required after 5th July 2007 and the centre should put measures in place to ensure compliance after that date.

A formal documented service level agreement does not currently exist for contingency services.	A service level agreement for contingency services to be formally documented.	Within six months.

Comment [C3]: Was this required in the 6th CoP?

Recommendations	Time scale
Male patients undergoing PESA operations have their consent forms filed within the hospital urology notes. It was recommended that these consent forms should be filed within the lab files so that they may be accessed easily for purposes of auditing stored samples against consent.	Immediate.
Patients (female) who consent to their male partners using their embryos in the event of their death, should be provided with additional patient information pertaining to additional screening and registration as a donor requirements. This information should also include counselling details to discuss the implications of this option.	Immediate.
Recommendation was made to develop a protection of children policy for the unit.	Within 2 months
All administration staff to be provided with an annual appraisal and personal development plan (PDP).	As soon as possible.
A service contract should be organised for the low oxygen alarm within the laboratory.	As soon as possible.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
At the last inspection, the PGD scientist had tendered his resignation. Although an agreement for him to continue providing his services to the centre one day per week, it was recommended that the post be advertised for a replacement.	A fully qualified PGD operative has been employed to continue the work on a full time basis.
The centre was recommended to devise their own patient questionnaire and to audit the findings.	A patient questionnaire has been devised and is in operation at the centre. Staff at the centre provided the first audit at the inspection for the executive.
Additional ventilation was recommended within the cryostore for health and safety reasons.	Additional ventilation was added to the cryostore along with an automatic monitoring system to detect nitrogen within the atmosphere. It was reported however that the sensor for the automatic monitoring system had been fitted with a nitrogen dioxide detector rather than a liquid nitrogen detector. A replacement sensor had been ordered and was awaiting delivery. To compensate for this, the centre have ensured that the system is active at all times and will only change over to the automatic setting for the unit once the correct sensor has been installed.
Recommendation was made for all interpreters used at the centre to sign confidentiality disclaimers prior to providing translation services for patients.	All interpreters are now required to sign confidentiality disclaimers.
I was recommended that the air quality within the laboratory and treatment room be re-tested.	Air quality within the laboratory and treatment rooms were re-tested and results obtained showing that the air quality within these areas meets with the EU Tissue and Cells Directive requirements. A particle counter has also been purchased which will allow staff to conduct regular monitoring checks.
Weekend witnessing was not always performed contemporaneously.	Additional steps have been put in place to ensure that all weekend witnessing is now performed contemporaneously.
Maintenance contracts to be provided for the incubators within the laboratory.	Now in place.
Nursing policies to e documented and version controlled.	Now in place.
All policies and procedures to be version controlled.	Now completed.

Laboratory environmental checks to be performed daily as per the standard operating procedure.	Now being performed as per the standard operating procedure.
Emergency resuscitation trolley to be checked daily and a record maintained of the checks performed.	Now in place.
Recommendation was made to document a policy for the capture of data into the computer which matches the samples in storage.	Although the policy has not as yet been documented, the inspectorate was advised that this will be scheduled for the July shutdown using the IDEAS 5 new database. It was further advised that preliminary work has already been completed by the administration team to ensure that all patient demographic detail has been input into the system so sperm location details etc., can then be added.

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
• The PR is fully aware of his responsibilities, and has completed his PR entry program. • Despite the centre being in two distinct locations within the Glasgow Royal Infirmary, centre appeared to be well organised and sufficiently staffed for the numbers of treatment cycles being performed. • Staff reported that they were all well supported in their CPD requirements and in their roles. • The centre follows the Glasgow Royal Infirmary clinical governance and risk management policies. Evidence of risk assessments performed in 2007 include: - oocyte retrieval, semen analysis, embryo freezing, semen cryopreservation, filling of storage dewars, thawing of semen/embryos, moving/using trolleys in the recovery area and potential exposure to blood during venapuncture procedures. • The centre has now employed the services of a full time quality manager to assist with the development of the quality management systems, and continues to receive advice from an external advisor for continuous improvement of the services provided to patients. • The incident policy appropriately reflects the requirements of the HFEA and all incidents are reported as per the procedure. • The Finance Department at the HFEA reported no problems with payment of fees. • Evidence was sighted that an audit of “Integrated Care Pathways for IVF and ICSI Cycles” had been conducted on 2nd February 2007 based on 13 patients who had completed treatment. • The centre has a freeze-all embryo policy when a patient presents with more than 20 eggs at egg collection to avoid development of OHSS. This policy was followed for around 70 patients last year. It was noted from the centres records that this cohort had a high pregnancy rate when returning for a frozen embryo transfer (FET) cycle.

Areas for improvement
• The PR noted that although a “Letter of Intent” exists to provide contingency services between the Glasgow Royal Infirmary ACS and the unit at the Glasgow Nuffield Hospital, this has not been formalised into a service level agreement. The PR stated that this will be formalised within the near future.
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
Success rate assessment data obtained from the HFEA for the period 31st March 2002 – 1st April 2005 show that IVF/ICSI for age ranges 38 – 42 are higher than the national averages and for age ranges below 35 to 37 are significantly higher than the national averages. The same is reflected in the data for frozen embryo transfer. The three embryo transfer log was examined to show that only one three embryo transfer had been performed since the last inspection. This had been performed in accordance with the requirements of the HFEA and the centres policy.
Areas of firm compliance
• The PR stated that he is collaborating with the assisted conception unit in Aberdeen on a study into the provision of single embryo transfer. Where appropriate, patients who meet the necessary criteria for single embryo transfer are offered this as a choice at the unit. • The patients' notes inspected all provided evidence of a suitable "Welfare of the Child" assessment being performed. Any potentially difficult cases are discussed at a multidisciplinary meeting, and only when a general consensus of opinion cannot be reached as to whether to offer treatment or not is the case forwarded to the ethics committee. • Patients' notes were seen to be stored securely and with restricted access within the centre. Since the last inspection, all interpreters used at the centre are required to sign confidentiality agreements. • The PR noted that patients are advised during consultation of the types of treatments available to them. It was explained that this can sometimes be dependant upon funding and eligibility requirements set by the health boards. • Patients interviewed stated that at no time during their treatment cycles had their dignity or privacy been compromised. • The complaints procedure was evidenced as being in compliance with the requirements of the HFEA and was well publicised both in the waiting areas and in the patient information. Five complaints had been recorded since the last inspection of which four had been

resolved. The remaining "open" complaint had been raised by the patients MP regarding long waiting times associated with access to treatment and the application of funding. It was noted by the inspectorate that a resolution to this complaint could not be influenced by the centre.

- A patient questionnaire has now been devised for use within the unit and feedback from patients has been audited. Evidence from the centres audit showed that waiting facilities had scored lowest. This was also reflected in the responses received from the HFEA patient questionnaire. The PR stated that although additional waiting room space could not be made available, centre staff had re-organised some of the clinics reducing the overcrowding of the waiting room during most, but not all busy periods. Outcomes from the audit were fed back through the quality management group. Of the 35 HFEA patient questionnaires returned all included very positive comments relating to the staff and the treatment services that had been provided to them at the centre.
- Counselling services are provided free of charge to all patients and are conducted within the counsellors office away from the unit. She stated that the provision of a room on the unit could also be made available if the patients preferred to be seen there. The counsellor stated that all notes are kept in a locked storage cabinet to which only she has has access to. The counsellor is appropriately qualified and a member of BICA, and received one and a half hours of supervision monthly. She attends the multi-disciplinary meetings wherever possible and feels included in the unit. A counselling audit provided at the inspection showed that between 1st April 2006 and 31st March 2007, a total of 557 counselling session had been recorded. It was further noted that this included 47 telephone consultations (a rise of 38% on the previous year) from patients seeking information and advice about the lack of donor sperm and consideration for seeking treatment abroad.

Areas for improvement

- The PR stated that storage of samples for patients under the age of 18 was on occasion provided, although there was no policy for the protection of children in place. It was further noted that the age of consent in Scotland was 16 years of age. It was recommended by the inspectorate that a policy for the protection of children be documented to cover all eventualities of the service being increased to cover a lower age group of patients wishing to store samples.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Egg sharing is not provided at the centre.
Donor selection.
Surrogacy.

Evaluation

Some improvement 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
• All areas were considered suitable for purpose (with the exception of the waiting area during busy periods) by the inspectorate. It was noted however that centre staff had made efforts to reduce congestion in the waiting room by re-organising some of the clinics. • The cryostores was evidenced as having been fitted with additional extract ventilation as recommended in the previous report. An automatic sensor and monitoring system had also been installed, however, it was reported that due to an incorrect sensor being fitted (to detect nitrogen dioxide rather than liquid nitrogen), the system was set to a continuous setting until the sensor was replaced appropriately. A replacement sensor had been ordered. • There were 18 dewars within the cryostore plus two spare tanks. With the exception of the emergency tanks, all were appropriately alarmed and connected to an auto-dial facility. Evidence was seen that the tanks are measured and filled on a weekly basis • The cryostore was seen to be secure with restricted access to authorised staff only. • Evidence was provided for equipment servicing and maintenance schedules which covered all critical equipment. Evidence was also provided to show that a maintenance agreement for the centres incubators was now in place, as recommended at the previous inspection. • Evidence was provided to show that the emergency crash trolley had been checked daily. • Emergency backup is supplied to the centre via a backup generator. • Evidence was provided to show that all environmental monitoring was performed daily in accordance with the centres' standard operating procedure. In addition, new environmental monitoring equipment has been purchased including data loggers which will chart the temperature of the incubators, hot blocks, fridges and freezers within the laboratory. • Since the last inspection, air quality within the laboratory and treatment areas has again been tested. Results obtained show that these meet with the requirements of the EU Tissue and Cells Directive. In addition, the centre has purchased a particle counter and a regime of regular testing and monitoring has been commenced. • Since the last inspection, the centre has purchased an additional ultrasound machine. Evidence was provided of training supplied to staff in its use, and it was further noted that the representative for the scanning machine was scheduled to return to the unit, three months after the initial training course to provide additional training. Staff who had attended the training, and assessed as being competent in its use, were provided with certificates of competence for their training folders.

Areas for improvement
• The waiting area for patients (on Friday mornings) can sometimes become overcrowded. Although efforts have been made to reduce congestion at other times, it has not been possible to reschedule monitoring appointments on Friday mornings. • It was noted that there is currently no service contract for the low oxygen alarm. It was agreed that this would need to be organised within the near future.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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
The last HFEA Operational Audit was conducted between 10th and 11th January 2007. The audit found adequate systems in place to record and submit data however staff absence had affected the timeliness of reporting. It was explained during the inspection that the administrator responsible for submitting the data had been on maternity leave but had since returned. The centre has now purchased the IDEAS database for treatment entry which also had some compatibility issues with the HFEA EDI system. These issues will be resolved in the near future. The PR and administrator noted that the centre will be closing down in July for a period of two weeks during which time the administrative staff will concentrate on ensuring all data is up to date. Ten sets of patient notes were reviewed during the inspection. Whilst all relevant consents were located within the notes, and evidence was seen that an appropriate "Welfare of the Child" assessment had been conducted, it was noted that in three sets of notes, the female patient had consented their male partners using her embryos posthumously however, the centre had not conducted the additional tests or registered the female as a donor. This was brought to the attention of the PR who stated that this will be addressed.
Areas of firm compliance
• All patient information reviewed provided at the inspection reflects current legislation, was version controlled and written clearly. • All patients interviewed stated that the information they had been provided with before and during the course of their treatment had been complete. They also commented that in the event that they had any questions regarding any aspect of their treatment, they would not hesitate to contact a member of the centre staff for an explanation. • The centre has a complete quality manual in place and all policies and procedures evidenced were version controlled and contained a review date.
Areas for improvement
• Female patients who consent to the posthumous use of their embryos must be screened and registered as donors for this request to be progressed. • Additional effort is required to ensure that all data for submission to the HFEA regarding patient treatments is brought up to date.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement 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	5
NMC registered nurses	12
HPC registered scientists	7
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	8 x administration staff, 2 x nursing care assistants, 1 x independent counsellor and 4 x laboratory staff.

Summary of laboratory audit
The centres dewar audit was provided pre-inspection showing that an audit of dewars was conducted between 9th and 13th April 2007. The report concluded that all samples of gametes and embryos had been accounted for. A number of administrative errors were found where discrepancies were identified with a number of straws not being deducted from the dewar record book. It was noted that the correct information had been recorded however in the patient notes. These were corrected.
Summary of spot check of stored material
Two sperm samples were checked from the tank to the records and two sperm samples were checked from the records to the tanks. No discrepancies were recorded. Two embryo samples were checked from the tank to the records and two embryo samples were checked from the records to the tanks. Again, no discrepancies were recorded.
Areas of firm compliance
• Staff were seen to be recruited in sufficient numbers for the number of treatment cycles performed at the centre. • All staff interviewed stated that they were well supported in their continuous professional development (CPD), very thorough training logs were evidenced during the inspection showing evidence of training attended, induction programmes completed and competency sign-offs as appropriate. Evidence was also provided to show that a training-needs assessment had been completed for all staff. It was also evidenced that a series of talks are provided for staff at the regular weekly meetings, some of which were organised with

external advisers.

- A fully qualified PGD practitioner has been appointed since the last inspection to replace the operative who resigned his post. Evidence was provided to show that he had been issued with a very comprehensive induction plan which had been followed.
- A new environmental monitoring system had been installed and improvements were seen to have been introduced in traceability logging.
- The centre now participates in the NEQAS scheme.
- It was evidenced that changes to the policy on witnessing had been made since the release of the last HFEA alert.
- The policy on responding to dewar alarms was evidenced and seen to be very detailed. It was explained that all laboratory staff have a copy of this policy which is kept at home in the event of an alarm activating.
- With the exception of female patients consenting to posthumous use of their embryos (detailed below), all other consents were seen to have been completed appropriately and screening conducted in accordance with protocols.
- Air quality in the laboratory and treatment rooms meet with the requirements of the EU Tissue and Cells Directive.

Areas for improvement

- Female patients who sign posthumous consent or their male partners to use their embryos are not currently processed as donors. It was agreed that this would be rectified.
- Laboratory staff needs to tighten their policy on recording accurately within the dewar record book when straws are removed for thawing.

Areas for Consideration

- Samples of sperm preparation are witnessed at the beginning of the process but movement between the preparation tubes is not witnessed. The team believe that this process is effective and has minimal risk as only one set of samples is processed at one time and the labelled tubes are kept together in a polystyrene box.
- There is no witness at the time of movement of embryos between the culture dish and transfer dish – all dishes are placed in a larger dish and the labelling of these dishes is checked on the day before. The lab team stated that this system meets with requirements because it is a containment system and dishes remain within the main dish once checked.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvement required.

Report compiled by:

Name TONY KNOX

Designation Inspector

Date 1st June 2007

Appendix A: Centre Staff interviewed

Mr Robin Yates - Person Responsible
Five other members of centre staff.

Appendix B: Licence history for previous 3 years

2007
Licence Committee 14th May 2007 granted the variation of the centre licence in accordance with the requirements of the EU Tissue and Cells Directive.

2006
Interim inspection for treatment and storage 7th July 2006.

Research inspection to commence research project 7th July 2006.

Licence Committee 22nd March 2006
Application was presented for the centre to carry out PGD for Ornithine Transcarbamylase Deficiency. This is an X linked urea cycle defect which can lead to the accumulation of ammonia in the body, which can lead to irreversible brain damage, coma and death, even if promptly treated. This was approved. In addition, the centre applied to carry out PGD for Androgen Insensitivity Syndrome. This is a condition also known as testicular feminisation syndrome which is an X linked condition. This was also approved.

2005
Renewal Inspection 14 June 2005

2004
Licence Committee: 11 November 2004
Interim Inspection & variation of licence to add storage of eggs.
LC agreed to continuation of centre's licence with no additional conditions or recommendations. LC agreed to vary centre's licence to include storage of eggs
Interim Inspection 3 September 2004

2004
Licence Committee 5th April 2004
The Committee agreed to grant the Variation to include pre-implantation genetic diagnosis (PGD) for the balanced reciprocal translocation: 46,XX,t(4;16)(q25;q12.1)mat.ish t(4;16)(D4S2930-,16qtel48+;D16Z3+,16qtel48-,D4S2930+) AP-04-0042 on the Centre's treatment licence.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0037

Name of PR Dr Robin Yates

Date of Inspection 30th May 2007

Date of Response 1st August 2007

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

Page 7
Policy for witnessing – has been implemented. Registration/ screening of donors – protocol changed Teaching sessions in progress

Page 8
Pesa op consents – protocol changed. Consent - as above

Page 17
Data being transferred via EDI. All previous data backlog being dealt with.

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

Signed

Name Dr Robert WS Yates

Date 6th August 2007

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).

Page 13 The study with Aberdeen had to be abandoned as few patients wished recruitment. All patients are advised of the possibility of SET. Those with severe medical conditions or abnormalities in uterine shape etc are strongly advised to have SET

Page 19 The Scientist referred to as working towards registration is a research assistant in the University Department and would thus not be required to be HPC registered

Typographical errors
Page 5 NJS =NHS
Page 6 improvements have been *made* since …
Page 8 alb = lab

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