Licence Renewal Inspection Report for Treatment and Storage Centres

Newcastle Fertility Centre at Life
0017

Date of Inspection: 14 November 2006
Date of Licence Committee: 14 February 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	Bioscience Centre, International Centre for Life, Times Square, Newcastle upon Tyne, NE1 4EP
Telephone Number	0191 219 4740
Type of Inspection	Renewal
Person Responsible	Jane Stewart
Nominal Licensee	Mary Herbert
Licence Number	L0017-12-a
Inspector(s)	Debra Bloor Janet Kirkland Parvez Qureshi David Archard (Authority member and observer)
Fee Paid	Not at 31 January 2007
Licence expiry date	30 April 2007

Index

About the Inspection:

This inspection visit was carried out on 14 November 2006 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between 11 May 2006 and 14 November 2006. The report references the analysis of outcome data from the period March 2002 to April 2005 and additional information extracted from the register for the time period from 1 June 2005 to 31 May 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 is part of the Newcastle upon Tyne Hospitals NHS Foundation Trust and provides NHS and self funded treatments to patients in the North East of England. The centre has an active research programme.

The laboratories at the Centre for Life are undergoing a major refurbishment and since December 2005, egg collections, embryology services and embryo transfers have been carried out at licensed premises of the Royal Victoria Infirmary (centre 0248). It is anticipated that the facilities at the Centre for Life will be fully functional early in 2007.

The Person Responsible (PR) has been in post since 2004 and has appropriate qualifications and experience for the role.

Activities of the Centre for the time period from 01/06/05 to 31/05/06

Licensed treatment cycles (IVF/ICSI and FET)	582
Donor Insemination	152
Unlicensed treatments	Gamete intra fallopian transfer Intrauterine insemination Ovulation induction Surrogacy
Research	✓
Storage	✓

Summary for Licence Committee

The Newcastle Fertility Centre at Life has been licensed since 1992. The centre offers NHS and self funded treatment to patients from the North East of England.

A small number of regulatory issues were identified in the course of the inspection and these are summarised as follows:

- Not all staff were able to provide evidence of training and CPD;
- Some protocols and patient information require review.

A number of recommendations have been made in relation to these issues.

The HFEA has received feedback from 22 patients who have been treated at the centre. The majority of the responses are very positive: 18 patients reported having compliments about the treatment they have received while only 3 patients reported having any complaints.

The centre has been proactive in responding to the recommendations of the previous report.

The inspection team supports the renewal of the centre's licence.

Risk Assessment

Risk status 11% - low

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

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

Breaches of the Act or Code of Practice

None identified

Recommendations	Time scale
The PR should ensure that there is a robust procedure in place for the management of documents. A quality manager was reported to be developing a computerised document management system that is expected to be functional by January 2007.	To be monitored at the time of the next inspection.
The PR should review the WOC protocol to ensure that the protocol reflects the requirements of section 3.25 of the COP and monitor implementation of the protocol.	Review to be carried out within 3 months. Implementation to be monitored at the time of the next inspection.
The senior andrologist should consider formalising the assessment of any risk associated with the storage of donor sperm samples	At the discretion of the centre considering the imminent installation of new vapour phase cryopreservation dewars.
Written patient information should be revised where appropriate.	Within 3 months
The PR should ensure that there are robust systems in place to ensure that training (including accredited training where required) is undertaken. The PR should consider carrying out spot check monitoring of training to ensure that staff are suitably qualified for the tasks undertaken	To be monitored at the time of the next inspection
The centre should consider assessing the risks associated with the practice of asking patients to consent to storage at the time of embryo transfer.	At the centre's discretion

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
The PR agreed to review the incident reporting protocol and to ensure that staff, particularly members of the administration team, are made aware of the requirement to report incidents to the HFEA.	Members of the administration team that were interviewed in the course of the renewal inspection reported awareness of incident reporting.
The PR should distinguish between provision of counselling and information giving and ensure that counselling is provided by suitably qualified staff.	See section 2
The PR should consider how the uptake of counselling can be more effectively monitored to reflect the different patient groups (donors, new patients, existing patients etc) using the service. A more detailed audit should then be used to inform the centre's decision making in relation to a review of the accessibility and provision of the service.	See section 2
The PR should carry out an assessment of the risk of continuing to store material from patients who have had treatment that may have impaired their fertility in single storage vessels. A copy of this assessment should be submitted to the HFEA and the Trust.	Completed immediately post inspection
An audit of stored sperm samples should be completed as a matter of urgency to comply with the requirements of the COP and the possibility of splitting oncology samples within existing storage vessels during the course of the audit should be considered. If this procedure is considered to carry a risk then this should be assessed and a copy submitted to the HFEA and the Trust.	Completed immediately post inspection

Additional licence conditions and actions taken by centre since last inspection

Licence L0017-11 was issued with one recommendation. The centre had complied with the recommendation at the time of the interim inspection in 2005.

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
- Incident management
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
Recommendations made in the previous report have been addressed by the PR and issues related to the counselling service were commented upon extensively in the previous report. The HFEA licence and information on making a complaint are on display in the patient waiting area of the centre. The centre adopts the clinical governance strategies of the Trust. The unit has appointed a quality manager who is in the process of implementing a total quality management system. The 2002 CHI review[1] assessed the Trust as having achieved level III in clinical risk management. The Trust is part of the Clinical Negligence Scheme for Trusts and achieved a level 2 risk management assessment in February 2005[2]. Staff reported that they would be confident to raise concerns with senior managers. The centre has a written adverse incidents policy and the incidents log was reviewed in the course of the inspection. A named person is responsible for coordinating the response to incidents. Staff interviewed in the course of the inspection reported awareness of incident reporting requirements. The average time to pay HFEA invoices over the last 6 months has been less than 60 days.
Areas for improvement
Some of the documents submitted to the HFEA in support of the application showed evidence of version control. However, welfare of the child assessment protocols submitted to the HFEA required revision to reflect changes in practice. The PR reported that all protocols are currently under review and that the centre is in the process of implementing an electronic document management system. The PR should ensure that there is a robust procedure in place for the review and management of documents.

[1] Clinical Governance Review Report Published by the Commission for Health Improvement, February 2002
[2] As reported on the NHS Litigation Authority website.

The centre reports having a well defined organisational structure but the self assessment completed by the centre comments that the system requires some improvement. These comments suggest that centre staff are already aware of issues relating to governance and quality management. Progress in improving systems should be monitored at the time of the next inspection.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Risk management Contingency arrangements Business planning

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)
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing

Live Birth Rates

In the time period from 1 June 2005 to 31 May 2006 the centre provided 582 cycles of IVF and ICSI treatment for 463 patients and 152 cycles of DI for 63 patients. Clinical pregnancy rates for the same time period and live birth rates for the preceding year are as follows:[3]

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle 01/06/05 to 31/05/06	20%	19%	30%	19%	10%
Live birth rate per treatment cycle 01/06/04 to 31/05/05	20%	30%	23%	17%	11%

Analysis of HFEA held register data for the time period March 2002 to April 2005 and comparison with national statistics showed that the centres success rates are in line with national statistics with the following exceptions: live birth rates following IVF and ICSI in patients aged between 35 and 37 and between 40 and 42 years are significantly lower than the national average; live birth rates following frozen embryo transfer (FET) in patients aged between 38 and 42 years are significantly lower than the national average.

The PR commented that with regard to the highlighted areas of apparent reduced performance, there are a number of confounding factors;

- The centre reports all cancelled cycles. If other centres fail to do this, this could affect national means, particularly in the older groups;
- Patient selection is likely to be much more variable in older age groups which would be reflected in the unit vs. national data;
- The numbers of women treated in older age groups is smaller which makes the data less robust.

The PR also commented that the unit has an extremely low three embryo transfer rate across

[3] Non verified information extracted from the HFEA register which may be subject to change

all ages and that the HFEA data analysis does not appear to have been adjusted to reflect this, nor has any national comparison been documented.

Evidence of the discussion of pregnancy rates was observed in the minutes of a management meeting.

Areas of firm compliance

The centre has a written protocol for carrying out a welfare of the child assessment (WOC) and evidence from patient records confirms that assessments are usually completed before treatment is provided. Staff reported being involved in meetings where issues related to WOC assessment are raised: no minutes are kept for the meetings where WOC issues are discussed.

Patient records are stored in locked filing cabinets in areas that are accessed by licensed personnel only. Staff interviewed in the course of the inspection reported awareness of confidentiality requirements. Procedures are in place to minimise the possibility of reoccurrence of administration errors that have previously led to breaches of patient confidentiality.

Two patients agreed to meet with inspectors on the day of the inspection. Both patients confirmed that their dignity and privacy had been respected in the course of treatment.

The centre adopts the Trust's complaints policy and responds to complainants within locally specified timeframes. The centre maintains a log of complaints and this was reviewed by the inspection team.

The HFEA has received feedback from a 22 patients who have received treatment at the centre over the last two years. The majority of the responses are positive: 18 patients reported having compliments about the treatment they have received while only 3 patients reported having any complaints. The only significant number of negative comments relate to the accessibility of counselling services: 10 of the 22 (45%) patients who provided feedback commented that the counselling service is inaccessible. Nationally, 31% of patients providing feedback comment that counselling is inaccessible.

This issue was raised in the course of the interim inspection in May 2006 and was commented on in the report of that inspection. In relation to this issue, the PR commented that the number of patients providing feedback represent only a very small minority of the patients treated by the centre. If the centre is assumed to treat approximately 500 patients per annum then feedback was provided by less than 5% of the patients provided with treatment. The PR also considers that the closed nature of the question in the HFEA questionnaire which requires a yes or no answer means that there will always be the appearance of dissatisfaction even if that is not the intention. The PR also reported that the centre intends to devote a portion of a forthcoming re-audit of patient satisfaction to the subject of both implications and therapeutic counselling in the clinic.

Provision of counselling was discussed at length in the course of the inspection. As at the time of the interim inspection, all implications counselling is provided by members of the

clinical and nursing teams. Again, this issue was raised at the time of the interim inspection and the PR commented that it is the view of the unit that that implications counselling is best carried out in the first instance by individuals who are well versed in and involved in clinical practice and it is arguable that individuals whose specialty is therapeutic counselling are in the best position to discuss those implications or that information. In the course of the renewal inspection, the inspection team saw evidence in patient records that all patients receiving treatment with donated gametes are counselled about the implications of their treatment and members of the nursing team reported complete confidence in their role in providing the service. It was noted that in units where implications counselling is only provided by the professional counsellor, when patients refuse the offer of counselling, they engage in no discussion about the implications of their treatment. The PR considers that clinical and nursing staff receive appropriate training for their counselling role in the course of their professional training. Subsequent to the inspection, the PR confirmed that some members of the nursing team have participated in relevant counselling related CPD.

Therapeutic counselling is provided by an appropriately qualified counsellor (evidence of the counsellor's qualifications and CPD were not reviewed in the course of the inspection) and the written records of the professional counsellor are kept securely and separately from other patient records. A counselling audit was submitted to the HFEA that reported 38 referrals for therapeutic counselling in the period from October 2005 to September 2006. Within this time period the centre treated 490 patients and this represents a therapeutic counselling uptake of approximately 8%.

The centre recruits sperm donors and provides IVF treatments involving egg sharing arrangements. The records of a small number of prospective donors were reviewed and these showed evidence of appropriate screening. The centre advertises for sperm donors in a local magazine. It was noted that up to the time of the renewal inspection the advert advised prospective donors that a payment of £15 could be made to cover expenses. The senior andrologist acknowledged that this now contravenes the requirements of Chair's Letter CH906)01 and reported that the advertisement has now been revised. The documentation of the payment of expenses to donors was discussed although as yet no donors have been recruited since the change in guidelines. The senior andrologist was fully aware of the requirements of the guidelines.

Donors are screened for HIV and hepatitis infection before any sperm is stored but samples are not quarantined pending the repeat screen at 180 days. The senior andrologist considers the risk of seroconversion following donation and/or cross contamination during storage to be so low as to remove the need for quarantining. The formal documentation of an assessment of any risk should be considered.

Evidence was provided that the export of gametes has been carried out in accordance with general directions.

Areas for improvement

The records of a patient who was refused treatment in the time covered by this report were reviewed in the course of the inspection. Although the refusal was documented, the rationale behind the decision was not. Treatment centres are expected to record information that has

been considered in respect of the welfare of the child and the record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment (section 3.25 of the 6th Code of Practice – COP). The PR should review the WOC protocol to ensure that the protocol reflects the requirements of the COP and monitor implementation of the protocol.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs) Choice of treatments

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
The premises appeared suitable on the day of the inspection and two patients interviewed in the course of the inspection confirmed that they had found the premises to be appropriate. Embryos and gametes are currently stored in the andrology laboratory. The laboratory is fitted with a low oxygen level alarm and access to the area is restricted to licensed personnel. Evidence of monitoring of equipment performance was seen in laboratory logs and evidence of the maintenance of a sample of key pieces of laboratory equipment was provided. Staff interviewed in the course of the inspection reported awareness of incident reporting requirements and were familiar with the procedures. The centre maintains an incidents log which was reviewed in the course of the inspection. Staff interviewed in the course of the inspection demonstrated awareness of HFEA Alerts: the PR disseminates information from Alerts and evidence of the routine discussion of Alerts was observed in the minutes of management meetings. Key pieces of laboratory equipment are connected to an uninterrupted power supply in accordance with the recommendations of Alert 20. Staff, including recently appointed members of staff, reported that they would feel confident to raise concerns and/or issues with senior managers.
Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No 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
- Record keeping

Outcome of audit of records
Twelve sets of patient records were reviewed in the course of the inspection. In nine sets of records, the paperwork was present, correctly completed and compatible with treatment. In two sets of records there was no evidence of completion of a welfare of the child assessment. Subsequent to the inspection the PR confirmed that WOC self assessment forms could not be located for the two sets of patients whose records were reviewed. The PR commented that both sets of patients are reported to have been through a prolonged period of treatment and assessment and whilst the evidence may be missing, WOC issues have been covered to the PR's satisfaction. In one set of records, the patient's wishes after death were incomplete. Subsequent to the inspection the PR confirmed that the couple had been contacted and asked to clarify their wishes.
Areas of firm compliance
Patient information was reviewed in some depth prior to the inspection and a report of the review was provided to the PR and senior andrologist. Information was largely clear and comprehensive. The provision of verbal and written information was documented in a sample of the patient records reviewed in the course of the inspection. An operational audit completed at the centre in November 2005 concluded that there was evidence of both late and outstanding reporting. However, in the time period from March 2006 only 3% of chargeable treatment forms were submitted late to the HFEA.
Areas for improvement
Written patient information requires some improvement. Specifically, not all patient information documents the patient or donors right to withdraw their consent; the risk of cross contamination of cryopreserved material; the statutory duty to asses the welfare of any child born as a result of treatment; the screening tests that gamete donors are subject to. Information for sperm donors should be revised to reflect that a flat fee payment of £15 can no longer be made and information and consents for patients undergoing donor insemination

should be revised to reflect that an unmarried male partner will have parental responsibility only if he registers as a child's father on the birth certificate.

It remains the centre's routine practice to ask patients to complete consent to storage forms only when it is known that suitable embryos are available to store. Patients are also screened for HIV and hepatitis infection at the same time. A patient interviewed in the course of the inspection commented that although the consent forms were "challenging", there had been enough time to consider the implications of providing consent to storage. However, the centre should consider assessing the risks associated with this practice, specifically, that both gamete providers may not be available to complete consents or have blood samples taken for the detection of infectious conditions.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Protocols

Evaluation
Some improvement needed

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:

- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Staff competence, qualifications, training and CPD

Staff

GMC registered clinicians	7 (including 2 consultants, 1 clinical assistant, 2 specialist registrars, 2 research registrars)
NMC registered nurses	10 (including 1 senior nurse, 7 staff nurses, 1 theatre nurse and 1 research sister)
Nursing support workers	2
HPC registered scientists	5 (3 senior and 2 qualified)
Trainee scientists	1
Counsellors	1
Medical technical officers	3
Support staff (receptionists, record managers, quality and risk managers etc)	9

Summary of laboratory audit
An annual audit of cryopreserved material was carried out between April and August 2006. No discrepancies were observed while carrying out the audit of stored embryos. Six anomalies (estimated by the centre to represent an error rate of 0.65%) were identified and rectified during the audit of cryopreserved semen samples.
Summary of spot check of stored material
A spot check audit of two sperm samples from records to tank and one sample from tank to record was completed. No discrepancies were observed.
Areas of firm compliance
A small number of procedures were observed in the andrology laboratory and these appeared to be carried out in accordance with protocol. The laboratory is suitably equipped to minimise any risk from the handling of biological samples. Resuscitation equipment is present on site and a member of the clinical team reported that they had received training in the provision of advanced life support. The resuscitation equipment had been checked on the day of inspection. All clinical staff are registered with the General Medical Council. The PR is also on the

specialist Obstetrics and Gynaecology and Reproductive Medicine registers. Embryologists are registered with the Health Professions Council with the exception of one trainee embryologists who is working towards registration through the completion of the Association of Clinical Embryologists certificate. All members of the nursing team are registered with the Nursing and Midwifery Council.

The continued professional development (CPD) of the PR and other members of the consultant clinical staff is monitored by the Royal College of Obstetrics and Gynaecology (RCOG). The PR confirmed that she completed an RCOG validated course of CPD in July 2006. A junior member of the clinical team reported that she has completed a number of training courses including advanced life support training and that she would be receiving mandatory training in November 2006. She also reported that she plans to attend a number of external meetings in the next year.

A recently appointed member of the administration team provided evidence of participation in training and demonstrated awareness of incident reporting requirements.

Members of the nursing team were able to provide evidence of monitoring of competency in ultrasound scanning although evidence of completion of an accredited training course was not provided. Subsequent to the inspection, the PR confirmed that some members of the nursing team have received relevant counselling related CPD.

Areas for improvement

Not all staff interviewed in the course of the inspection were able to provide evidence of participation in mandatory health and safety or basic life support training. However, subsequent to the inspection the PR reported that all relevant staff undertook cardio pulmonary resuscitation training in November 2006. Also subsequent to the review of the draft report, the PR reported that at the time of the inspection training records were held by the Trust but that in compliance with the requirements of the centre's quality management system, staff would maintain individual training records in future.

The PR should ensure that there are robust systems in place to ensure that required training is undertaken. The PR should consider carrying out spot check monitoring of training to ensure that staff are suitably qualified for the tasks undertaken.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Assessment of patients and donors

Clinical practice

- At the time of the inspection egg collection, embryology and embryo transfers were taking place at the licensed premises of the Royal Victoria Infirmary and it was not possible to observe or evaluate clinical practice.

Recruitment and retention of staff

Evaluation
Some improvement required

Report compiled by:

Name…Debra Bloor…….

Designation……Inspector……..

Date……7 December 2006……

Appendix A: Centre Staff interviewed

The PR and nine other members of the unit's staff were involved in meetings with the inspection team.

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expires
L0017/11/a	Treatment with Storage	01/09/2005	30/04/2007
L0017/10/b	Treatment with Storage	11/08/2004	30/04/2007
L0017/10/a	Treatment with Storage	01/05/2004	30/04/2007
L0017/9/d	Treatment with Storage	07/07/2003	30/04/2004

L0017/11/a

No conditions

Recommendation

- That the Person Responsible should get written confirmation that the witnessing protocols in use at the Hexham transport centre are in line with those protocols in use at Centre 0017.

L0017/10/a/b and **L0017/9/d**

Conditions

- The PR must ensure that the centre has made all reasonable efforts to satisfy itself that the GP of each prospective parent knows no reason why either of the parents are not suitable for the treatment to be offered (including anything which might adversely affect the welfare of any resulting child or child of the family.)
- The PR must ensure that consent to treatment/storage/use is given in accordance to the HF&E Act 1990 and the Code of Practice for the time being in force, and that the patients after death wishes are clearly stated.

Recommendations

- That patients undergoing ICSI should receive the information sheet from the Centre, suitably updated to take account of the latest published evidence, plus the latest version of the HFEA leaflet on ICSI.
- That the Person Responsible ensures that the documentation used by the transport centre is reviewed with particular regard to consent to disclosure and Welfare of the Child assessment.
- That the Person Responsible must ensure that the patient's consent is obtained before approaching his or her GP and that consent to disclosure forms are signed as soon as it has been agreed to proceed to treatment. To facilitate this the consent to disclosure form should be separated form the consent to treatment form.
- That the centre amends the patient information to incorporate the points raised in section 8 of the inspection report, viz.
    - Epilepsy be listed separately to mental disorders;

- Health Authorities changed to read Primary Care Trusts;
- Year of the HFE Act be corrected to 1990;
- Cytomegalovirus be written in full;
- No mathematical signs for greater than or less than used
- That the Person Responsible should endeavour to ensure that couples consent to posthumous use is compatible, and that all consent forms are completed fully and dated.
- That the Person Responsible reports all adverse incidents to the HFEA in line with section 2.24 of the Code.

Appendix C: RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…0017……

Name of PR……Jane Stewart…….

Date of Inspection…2006-11-14……..

Date of Response… 2006-12-29……

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