



**Licence Renewal Inspection Report for Treatment  
and Storage Centres**

**James Cook  
0055**

**Date of Inspection: 4<sup>th</sup> July 2006  
Date of Licence Committee: 11<sup>th</sup> October 2006**

## CENTRE DETAILS

Centre Address	The Department of Reproductive Medicine James Cook University Hospital Middlesbrough
Telephone Number	01642 854856
Type of Inspection	Renewal
Person Responsible	Mr Philip J Taylor
Nominal Licensee	Mr R Hutchison
Licence Number	L0055-13-a
Inspector(s)	Janet Kirkland Dr. Victoria Lamb Delia Kelleher
Fee Paid - date	Not yet invoiced
Licence expiry date	31 January 2007

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## **About the Inspection:**

This inspection visit was carried out on 4 July 2006 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between September 2005 and July 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](http://www.hfea.gov.uk).

## Brief Description of the Centre and Person Responsible

The centre is located within the James Cook University Hospital and operates within the South Tees Hospitals Trust. Patients may be referred privately or by seven Primary Care Trusts. The Person Responsible informed the inspection team that this resulted in approximately 50% being funded by the NHS and the remaining 50% privately.

In the previous 12 month period the centre carried out approximately 300 licensed treatments, including ICSI, IVF, egg share, egg donation and DI.

The centre is located over two floors of the University Hospital. The first floor comprises the waiting area, file stores, administration office, consulting rooms and examination rooms. The gynaecology ward is located at the end of the corridor. The ground floor comprises a men's production room, laboratories, cryostore, and main hospital gynaecology theatre and recovery room.

Mr Taylor is based at the centre on a full time basis. He also holds the position of Accredited Consultant and is a Fellow of the RCOG. He has been at the Centre since 1986.

## Activities of the Centre

IVF	65
ICSI	179
FET	23
Egg share	4
Egg donation	5
Donor Insemination	11
Unlicensed treatments	IUI
Research	None
Storage	Yes

## Summary for Licence Committee

Centre 0055 was considered by the inspection team to be well organised. The premises are fit for purpose.

Documentation provided for the inspection, including patient information, was of a high standard.

Patient feedback from questionnaires received at the HFEA were complimentary about the centre, staff and standard of care.

The centre has a good history of regulatory compliance and there are no conditions on its current licence.

The inspection team recommend the renewal of the centre's licence for five years.

### **Risk Assessment**

The risk score for this centre using the HFEA risk matrix is 16%

### **Overall judgement of the effectiveness of the centre**

<b>No Improvements required</b>	<b>Some Improvement required</b>	<b>Significant Improvement required</b>
	✓	

### **Evaluations from the inspection**

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

## Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Code of Practice 8.20 - In the previous 12 month period two 3 embryo transfers had been performed for women under the age of 40. The Person Responsible informed the inspection team that the decision to transfer 3 embryo's was based on previous treatments. Evidence of this was seen to be documented in the three embryo transfer log.		Immediate

## Non-Compliance

Area for improvement	Action required	Time scale
None		

## Recommendations

## Time scale

Patient information required minor updating regarding the change in legislation for donor anonymity.	Immediate
All protocols to be version controlled	April 2007
It was reported that there was little funding provided by the Trust in addition to difficulty in taking time off from clinic duties to attend training days.	

**Proposed licence variations**

None

**Changes/ improvements since last inspection**

<b>Recommendation</b>	<b>Action taken</b>
To monitor individual ICSI practitioners results on a three monthly basis.	Evidence of ICSI results were supplied with the renewal application. These were reviewed by the inspection team and found to be satisfactory.

**Additional licence conditions and actions taken by centre since last inspection**

**C** Not applicable

## 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

<b>Areas of firm compliance</b>
<p>The centre was assessed as being well organised. The PR is established at the centre and has been in this role for a number of years.</p> <p>It was noted that patients attend the general gynaecological day unit for oocyte collection and embryo transfer. One of the members of the centre's nursing team accompanies the patients when possible and also provides talks and training events for the theatre team.</p> <p>The team hold fortnightly multidisciplinary meetings and minutes of meetings from May and June 2006 were reviewed by the inspection team. It was noted that communications from the HFEA, including Alerts were disseminated and discussed at these meetings.</p> <p>All staff interviewed were aware of the HFEA incident reporting system and the centre HFEA incident file was reviewed by the inspection team. No incidents have been reported to the HFEA since the previous inspection.</p> <p>The PR reported that a verbal agreement was in place with centres at Hartlepool and Gateshead in the event of emergency cover being needed and the unlikely event that treatment cycles were unable to be performed at the centre.</p>
<b>Areas for improvement</b>
<p>While centre staff reported staffing levels as adequate, they were of the opinion that additions to the nursing and embryology team would allow more time for staff to attend training events.</p>
<b>Executive recommendations for Licence Committee</b>
<p>None</p>

Areas not covered on this inspection
None

Evaluation
No 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
The live birth rate for April 2004 to March 2005 was 21 %.

## Areas of firm compliance

A suitable welfare of the child procedure is in place. This involves discussion at multi-disciplinary team meetings if concerns are raised. The PR writes to patients if treatment is to be refused. Records of assessments were seen to be included in patient notes.

Patient records are stored in a locked room with entry restricted by keypad locks. Current records were stored in locked cabinets in the nurse's office.

Patient information describing treatment options is clear and comprehensive. The PR reported that he thoroughly discusses with patients their chances of success taking into account various aspects such as age, BMI, health and cause of infertility. He has designed an electronic system whereby all this information is logged and sorted. This was demonstrated for the inspection team.

The patient areas including waiting room, and consultation room were all considered by the inspection team to be fit for purpose with consideration for patient privacy and dignity. The counselling room had been seen on a previous inspection by the lead inspector and was considered to be fit for purpose. Surgical procedures and embryo transfers are carried out in the main gynaecology theatre suite. The pre and post operative area were seen by the inspection team and found to be satisfactory.

The centre has reported no complaints in the previous 12 months. The complaints folder was viewed by the inspection team. If patients want to make a complaint they can do this through the hospital Patient Advisory and Liason Service (PALS). This was clearly advertised in the waiting room.

Patients are invited to give feedback via a questionnaire. Any concerns requiring immediate attention are discussed at team meetings and relevant action taken. Feedback from HFEA questionnaires were overwhelmingly positive about the care received at the centre. Eighty three have been received over the past two years.

Counselling is offered free of charge to NHS patients. A counselling audit for the period April 2005 – April 2006 was supplied with the inspection papers. A total of 59 counselling sessions were reported as having taken place, 35 for support and 24 implications. The counsellor attends team meetings, this was evidenced in the meeting minutes. She also attends patient information evenings. Of the 83 questionnaires returned to the HFEA, 80 stated that they had been made aware of the counselling service.

Protocols and patient information for egg sharing were seen by the inspection team and these were considered to be satisfactory. There is an active egg sharing/donating programme.

The centre is currently trying to recruit sperm donors.

<b>Areas for improvement</b>
<p>The scientific inspector considered the men's room to be "private but not ideal". The senior scientist informed the inspection team that he had received a complaint regarding the décor in the men's room. One questionnaire returned to the HFEA expressed dissatisfaction with the men's room.</p>
<b>Executive recommendations for Licence Committee</b>
None
<b>Areas not covered on this inspection</b>
<p>The counsellor was unable to attend the inspection, however an audit of counselling was provided with the inspection papers. The lead inspector had interviewed the counsellor on a previous inspection.</p>
<b>Evaluation</b>
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

<b>Areas of firm compliance</b>
<p>The centre is situated within an NHS general hospital located over two floors. All rooms were found to be fit for purpose. Patients requiring ultrasound scans attend the general X ray department.</p> <p>Clinical procedures are carried out in the gynaecological day unit with appropriate emergency facilities. The Person Responsible informed the inspection team that there is always an anaesthetist present within the theatre suite when procedures are being carried out. He also informed the inspection team he is experienced in cardio-pulmonary resuscitation. All members of the clinical team undertake mandatory basic life support training.</p> <p>Dewars in the laboratory were seen to be locked and alarmed. Records for topping up dewars were seen by the scientific inspector. A low level oxygen alarm was seen to be in place. This is calibrated six monthly and records for this were seen by the scientific inspector.</p> <p>There are systems in place for maintenance of equipment and a selection of maintenance records was seen by the scientific inspector.</p> <p>The cyostore has a warning on the door forbidding entry in the event of the alarm sounding</p> <p>All staff interviewed were aware of the incident reporting systems.</p>
<b>Areas for improvement</b>
None
<b>Executive recommendations for Licence Committee</b>
None

Areas not covered on this inspection

None

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

<b>Outcome of audit of records</b>
Eight patient records were reviewed at the inspection. These were found to be in good order with evidence of Welfare of the Child assessment, consent to disclosure and HFEA consents to use and storage. The consent to disclosure was absent for one of the records. This was discussed with the staff and they were advised to address.
<b>Areas of firm compliance</b>
Patient information is provided both verbally and in writing. The written information was reviewed by the inspection team and found to be clear concise and sensitively written. HFEA patient questionnaires reflected patient satisfaction with provision of information 83 responses were received out of which 81 stated that they were satisfied with the amount of information they were given.  No issues were raised by HFEA registry regarding the reporting of treatment cycles or completeness of registry returns.
<b>Areas for improvement</b>
Patient information required minor updating regarding the change in legislation for donor anonymity.  Some protocols were not version controlled
<b>Executive recommendations for Licence Committee</b>
None
<b>Areas not covered on this inspection</b>
Not applicable
<b>Evaluation</b>

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
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

### Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	5
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	4 administrative staff. 1 part time counsellor.

### Summary of laboratory audit

An audit was performed in the previous twelve month period. It was reported that gametes and embryos in store corresponded to those listed.

### Summary of spot check of stored material

Two embryos and two sperm samples were tracked from notes to dewars and dewars to notes. No discrepancies were found.

### Areas of firm compliance

The scientific inspector observed the receipt, processing and freezing of a sperm sample and confirmed that the patient was treated with dignity and respect and that witnessing was carried out.

The Person Responsible demonstrated to the inspection team an electronic system whereby continual audit of treatment results and team performance can be carried out.

Staff are attempting to recruit sperm donors and information for prospective donors including the screening required was seen by the inspection team. Check lists for information required and given to patients participating in donation programmes was also provided with the inspection papers.

Areas for improvement
Evidence of continuing education for the centre staff was seen by the inspection team. It was reported that there was little funding provided by the Trust in addition to difficulty in taking time off from clinic duties to attend training days.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
➤ PGD/ PGS Not performed at this centre.
Evaluation
Some improvement required

Report compiled by:

Name.....Janet Kirkland.....

Designation...HFEA inspector.....

Date.....July 4th 2006.....

**Appendix A: Centre Staff interviewed**

Person Responsible: Mr Philip Taylor

Five other centre staff

## **Appendix B: Licence history for previous 3 years**

First Licensed July 1992

### **2006**

*Licence Committee 8<sup>th</sup> February 2006*

The Licence Committee agreed to the continuation of the Centre's licence with no conditions

### **2005**

*Interim inspection 27<sup>th</sup> September 2005*

*Licence Committee 12<sup>th</sup> January 2005*

The Licence Committee agreed to the continuation of the centre's licence with no conditions and five recommendations

### **2004**

*Inspection visit 28<sup>th</sup> September 2004*

### **2003**

*Licence Committee 18<sup>th</sup> December 2003*

The Committee agreed to the renewal of the centre's licence for 36 months with no additional conditions and two recommendations

*Inspection visit 11<sup>th</sup> November 2003*

*Licence Committee 11<sup>th</sup> July 2003*

The Committee agreed to grant a temporary six month licence to allow the remainder of the renewal inspection to take place

*Inspection Visit 20<sup>th</sup> May 2003*

**Appendix C:**

**RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT**

Centre Number.....0055...

Name of PR..... Philip Taylor

Date of Inspection...4<sup>th</sup> July 2006

Date of Response...28<sup>th</sup> July 2006

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

Page 5: "I have been at this centre since 1986"

Page 7: "Recommendations - All protocols are dated and are archived at least annually. As the date is numerical, they do in effect have version numbers. We find that this is more useful than an arbitrary version number."

Page 12: "Counselling is offered free to NHS patients and to anyone having any sort of licensed treatment at this centre, no matter how funded. The only people who are charged separately for counselling are patients who have not had an NHS referral to this Centre, and who are not having treatment here. Effectively that means who are having treatment at another Centre, and who have never been seen in clinic here.

Page 14: "For main gynaecology theatre please insert gynaecology day unit"

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

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