Interim Inspection Report

The James Cook University Hospital
0055

Date of Inspection: 11th November 2008
Date of Licence Committee: 11th February 2009

Centre Details

Person Responsible	Mr Fayez Mustafa
Nominal Licensee	Robert Stewart Hutchison
Centre name	The James Cook University Hospital
Centre number	0055
Centre address	Department of Reproductive Medicine, Marton Road Middlesbrough Cleveland, TS4 3BW United Kingdom
Type of inspection	Interim
Inspector(s)	Bhavna Mehta
	Gill Walsh
	Lynne Nice
Fee paid	N/A
Licence expiry date	31/01/2012
NHS/ Private/ Both	NHS and Private

Index

About the Inspection:

This inspection visit was carried out on 11th November 2008 and lasted for 8 hours.

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 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.

Where recommendations are made the HFEA will provide details of <u>what</u> needs to be addressed but not <u>how</u> they should be carried out as this is the responsibility of the Person Responsible.

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 <u>www.hfea.gov.uk</u>.

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 self funded or funded by the NHS. The centre provided IVF and ICSI treatments and a small number of cycles involving egg sharing and/or egg donation.

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.

The Person Responsible has been registered on the GMC Obstetrics and Gynaecology Specialist Register since 2007 has been at the centre since 2006. The person responsible has completed the PREP and is based there full time.

Activities of the Centre[1] for the time period from 30/06/2007 to 01/07/08

In vitro fertilisation (IVF)	65
Intracytoplasmic sperm injection (ICSI)	241
Frozen embryo transfer (FET)	15
Intra uterine insemination (IUI)	
Gamete intrafallopian transfer (GIFT)	
Research	
Storage gametes/embryos	Yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for Licence Committee

The unit has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment that they receive. The centre has been proactive in the development and implementation of a quality management system.

Improvements should be considered relating to the following aspects of the centre's practice:

- Revision of the organisational chart;
- Payment of invoices;
- Control of documentation;
- Provision of mandatory update training;
- Revision of witnessing documentation;
- Revision of the complaints policy;
- Revision of the incidents reporting policy;
- Revision of the freezing witnessing protocol.

The inspection team would recommend that progress in addressing the issues outlined should be made within the timescales specified. The executive recommends the continuation of the centre's licence.

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, Standard Licence Conditions or Code of Practice:

The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The lines of responsibility, on the organisational chart submitted with the pre	The PR should review the organisational chart to ensure that the chart clearly defines	To be monitored at the next

inspection questionnaire (PIQ), were considered unclear for the clinical staff.	accountability and reporting relationships. (Standard licence condition A.10.1).	inspection
The centre uses the Trust's incidents policy, which does not reflect the centre's reporting obligation to the HFEA.	The PR should review the centre's incidents procedure against the requirements of CoP S.9.4.2.	To be monitored at the next inspection
The centre uses the Trust's complaints policy, which does not reflect the requirements of the CoP. The centre has not established a documented procedure for the resolution of complaints.	It is recommended that the centre review their complaints handling systems against the requirements of CoP S.9.2.2 and G.11.1.	To be monitored at the next inspection
Some documents provided with the pre inspection questionnaire were not uniquely identifiable.	The PR should ensure that all documents can be uniquely identified as required by S.5.2.6 and A.10.27.	To be monitored at the next inspection
Members of staff have not had their competency to perform designated tasks assessed	The PR should ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System and re-training undertaken when required. The PR should also ensure compliance with Licence condition A.10.11 and CoP S.6.2.9.	To be monitored at the next inspection
At the time of inspection, the centre had started to establish an effective system for monitoring and assessing laboratory, clinical and counselling practice. The centre needs to develop this system further by establishing an effective system that can demonstrate that procedures and outcomes are satisfactory.	It is recommended that the centre reviews the requirements of the CoP, in particular, S.9.5.3.	To be monitored at the next inspection.
The inspectorate was told that	The PR should ensure that	To be

risk assessments are carried out at Trust level, to identify hazards. However, the centre's specific processes, including processes such as witnessing and moving of gametes have not been risk assessed.	procedures are evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards in compliance with S7.8.3.	monitored at the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
At the time of freezing, the centre's protocol does not require that witnessing is cross referenced against a unique identifier.	The freezing protocol should be revised to ensure that to include a unique identifier to comply with G.13.8.2	To be monitored at the next inspection.

Recommendations

Area for improvement	Action required	Time scale
The minutes of meetings seen at inspection did not give a full record of all the discussions.	The centre may like to consider how they can ensure that there is an effective means for communicating information to staff and receiving suggestions from staff in line with S.6.2.13	To be monitored at the next inspection.
The centre's Quality Management System (QMS) is in the process of development and the centre should develop an internal audit process to determine whether the QMS satisfies the requirements of the CoP	The centre should consider all the requirements of the CoP, in particular, S.9.2.4; S.9.5.1 and S.5.2.2.	To be monitored at the next inspection.
The centre's protocol for transferring gametes and/or embryos is not complaint with the requirements of Alert 21.	The PR should review and revise the protocol in consideration of the requirements of Alert 21	To be monitored at the next inspection.
On the day of inspection, some patient records were seen in one of the examination rooms.	The PR should review the centre's procedures to ensure that the centre has clear security procedures to prevent unauthorised access to records. G 10 2 1 and S.33 (5) HF&E Act 1990	To be monitored at the next inspection.
Not all equipment seen at inspection was CE marked.	The PR should consider the requirements of S.6.4.1 when purchasing equipment and materials and seek local advice on the suitability and availability of CE marked equipment.	To be monitored at the next inspection.

A number of errors are outstanding in the electronic data interface (EDI) reporting of registrations, treatments and outcomes.	The PR should review the procedures for submission of HFEA register information to ensure compliance with Direction D.2008/6.	To be monitored at the next inspection.
On the day of inspection, an audit of storage consents identified that the centre's bring forward system SOP covers storage of sperm only.	This SOP needs to be extended to cover embryos to ensure compliance with CoP S.7.8.11 and to prevent a breach of statutory storage regulations and the requirements of schedule 3 of the 1990 HF&E Act.	To be monitored at the next inspection.
It was reported that air quality will be monitored every six months. It is recommended that air quality monitoring procedures are validated to provide documented evidence that air quality is maintained in the time intervals between testing (A.10.19).	It was reported that air quality will be monitored every six months. It is recommended that air quality monitoring procedures are validated to provide documented evidence that air quality is maintained in the time intervals between testing (A.10.19).	To be completed by the time of the next inspection.

Changes/ improvements since last inspection

Recommendations	Action Taken
Patient information required minor updating regarding the change in legislation for donor anonymity.	The centre has stated that this has been completed.
It was reported that there was little funding provided by the Trust for Continuing professional Development (CPD) in addition to difficulty in taking time off from clinic duties to attend training days.	The centre has stated that an administrative assistant and two full-time embryologists have been recruited. Plans to recruit one more nurse have been approved by the management team. This increase in numbers will enable staff to attend training sessions.

Additional licence conditions and actions taken by centre since last inspection

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The Person Responsible (PR) has completed the HFEA Person Responsible Entry Programme (PREP) and is appropriately qualified and experienced for the role of PR in accordance with the requirements of Code of Practice (CoP): S.4.1.4: S.4.1.5). A Licence Committee (LC) approved the PR in September 2008. Arrangements are in place to provide managerial cover in the PR's absence. On the day of inspection, the premises appeared suitably equipped. The PR reported that many new staff have joined the centre in recent months and that the whole team are working well together to raise the standard of compliance and performance. The laboratory staff are working with the Quality Manager to develop the centre's Quality Management System (QMS). The Trust is to offer patients a third free cycle of treatment in the next financial year. This will increase the centre's workload. The PR is, therefore, with Trust approval, looking to recruit additional staff, especially nursing staff. The PR reported that the centre's current database was purpose built by the last PR and that on his retirement, the skill and expertise to use the database fully, has been lost. The PR is, therefore, currently discussing with the Trust's IT department, the centre's need for a new, user-friendly and more efficient database which will help the PR and his staff to develop procedures to ensure compliance with the requirements of the CoP. There are verbal agreements with Hartlepool, Gateshead and Newcastle IVF centres to provide contingency cover in the event of emergencies. A back up

generator, that is tested every four weeks, ensures continuity of service in the event of a power failure. Patients are provided with emergency contact numbers of key members of staff for contacting the centre out of hours.

At inspection, a sample of third party agreements was reviewed against the requirements of G.2.1.2 and was found to be complaint.

There is an effective means for communicating to and receiving information from staff. Departmental meetings are held every two weeks and departmental and team meetings are held monthly. Staff are updated of any changes by email and by accessing the Trust intranet. Staff are encouraged at meetings, to make suggestions to improve the service and evidence of this was seen in the minutes of meetings.

Areas for improvement

The organisational chart submitted with the pre inspection questionnaire (PIQ) reflected the structure and lines of responsibilities of the centre staff. However, the chart includes personnel who are not directly involved in the provision of fertility treatment. The lines of responsibility were considered unclear for the clinical staff as the chart does not indicate to whom they report. The chart also indicates two persons assuming responsibility for the centre and this needs clarification: this is potentially non-compliant with standard licence condition A.10.1.

The inspectorate was told that risk assessments are carried out at Trust level, to identify hazards. However, the centre's specific processes, including processes such as witnessing and moving of gametes have not been risk assessed. The PR should ensure that procedures are evaluated to identify potential hazards to laboratory staff and precautions put in place to minimise potential hazards in compliance with S.7.8.3.

The centre uses the Trust's incidents policy, which does not reflect the centre's reporting obligation to the HFEA. The Centre's documented procedure relating to adverse incidents should ensure notification of the HFEA, by the Person Responsible, of adverse incidents within 12 working hours of the identification of the adverse incident and submission of an adverse incident report form within 24 working hours and the subsequent provision of a confirmation/conclusion report in compliance with S.9.4.2 (c).

The centre's complaints policy was not displayed in the waiting area. The inspectorate was told that the centre feeds all complaints into the Trust PALS department and does not have its own complaints policy. The centre should review the procedures for handling complaints to ensure compliance with CoP S.9.2.2 and consider the guidance given in G.11.1.

The centre logs incidents and complaints on the Trust's electronic database and certain staff have access to this system. The incidents and complaints are investigated centrally in the Trust and feedback provided to the centre. The PR should review this system to ensure that non licensed personnel are not able to

access confidential identifying information which could lead to a breach of S.33 of the HF&E Act.

For the year up to February 2008, the average time taken to pay HFEA invoices was 37 days. This is potentially a breach of standard licence condition A.16.3. The Person Responsible should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.

Areas for consideration
The Trust adopts a no-blame culture, where all staff are encouraged to report incidents via an electronic system and the data collected is subsequently used to improve processes. Alerts are discussed at meetings of laboratory staff only. The PR stated that all Alerts, incidents and near misses are discussed at the fortnightly departmental meetings and that all incidents are reported to the HFEA within 12/24 hrs. The PR confirmed that incidents and Alerts are discussed under a standard agenda item. The minutes of meetings seen at inspection did not provide evidence of these discussions. The centre may like to consider how it can be ensured that there is an effective means for communicating information to staff and receiving suggestions from staff in line with the requirements of S.6.2.13
Executive recommendations for Licence Committee
The PR should review: 1. the organisational chart; 2. procedures for evaluating processes to minimise potential hazards; 3. complaints procedures and the display of information on complaints; 4. incidents reporting procedures and policy; 5. payment of HFEA invoices.
Evaluation
Some improvement required
Areas not covered on this inspection
All areas covered

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In 2007 the live birth rates resulting from IVF /ICSI cycles in all age groups were in line with national averages. In 2006, IVF/ICSI success rates (live birth rates) in patients aged below 35 years were in line with national averages. The centre performed less than 50 cycles in patients in age groups 38-39 years, 40-42 years and no cycles for patients over 42 years. Therefore no statistical analysis on the results for these groups has been performed. For all other treatment types, (FET and DI), less than 50 cycles were performed for each age group of patients in 2006 and therefore no statistical analysis of the results is possible. The PR reported that he has developed an elective single embryo transfer policy that is awaiting approval of the Senior Management Board. Last year, the centre's multiple birth rate was 27%.
Areas of firm compliance
The centre has a designated quality manager. The embryologists have been assisting with the protocols and other tools for the laboratory processes. Some documents reviewed at inspection had recently been updated and it was noted that access to documents is controlled as they were available to staff as password protected 'read only' documents. The centre holds information sessions for patients and feedback is obtained at these sessions from patients. The HFEA received feedback from 22 patients who received treatment at the centre in the time since the last inspection. Patient responses recorded a high

level of satisfaction with the service provided.

In the course of the inspection, a patient undergoing treatment at the centre, provided feedback on her experiences. The patient reported that her privacy and dignity have been given due consideration; she has experienced no difficulties in contacting the centre; the centre have made her aware of the counselling service. The patient considered staff to be professional and supportive and said that all procedures were fully explained.

Areas for improvement

None

Areas for consideration

The centre's Quality Management System (QMS) is in the very initial stages of development and the centre should develop an internal audit process to determine whether the QMS satisfies the requirements of the CoP (S.9.2.4.). The centre has not implemented procedures for evaluation and assessment to ensure continual improvement of the QMS (S.9.5.1), established quality indicators (S.9.5.2), developed a system for monitoring and assessing laboratory, clinical and counselling practice (S.9.5.3.) or carried out a management review of the QMS (S.4.2.9). Feedback from patients has not been gathered or evaluated although the centre is planning a patient satisfaction survey in January 2009.

It is recommended that the PR reviews the requirements of section S.9 of the CoP and ensures that procedures for the evaluation and improvement of the quality of the service provided are developed and implemented. The PR should also ensure that a management review of the quality of the service is carried out in line with the requirements of S.4.2.9.

Some of the documents provided with the pre inspection questionnaire did not show evidence of document control. It is recommended that a document control procedure be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use in line with the requirements of S.5.2.6 and A.10.27

Executive recommendations for Licence Committee

The PR should review relevant procedures in consideration of the requirements for:

1. Further development of the QMS
2. Document control procedures.

Evaluation

Significant improvement required.

Areas not covered on this inspection

All areas covered

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
The centre is situated within an NHS general hospital located over two floors. On the day of the inspection the premises and facilities appeared well maintained, and suitably equipped. Patients requiring ultrasound scans attend the general X-ray department. Arrangements are in place for cleaning, facilities maintenance and waste disposal. The clinical facilities and waiting areas are located on the first floor and seem to be furnished to a standard appropriate for licensed activities. The inspectorate was shown around the counselling facilities. These were provided in quiet, comfortable, private and confidential surroundings. The gynaecology day unit on the ground floor houses the laboratory, gynaecology day ward which includes a theatre where egg collections take place, a recovery area and sperm collection room. Entry to the day unit is controlled by use of swipe cards for staff and bell for patients. The centre has exclusive use of the unit at agreed times and days. All patients report to the day unit reception where they are admitted and then accompanied to either the sperm collection area or the ward. The storage facilities for gametes and embryos are secure. Access to the cryostore is by key with only certain centre staff having access. The centre has a documented procedure to deal with damage to dewars or non-conformities in storage conditions. At inspection, it was seen that all the tanks in the cryostore are alarmed, processes are in place to set the auto-dialler every night and disarm it each morning and staff participate in an on-call rota for responding to out of hours alarms. The cryostore contains 14 dewars: separate dewars are used for screened and unscreened embryos and sperm; released, quarantined, emergency and holding samples.

Evidence of air quality monitoring in all relevant areas of the laboratory was provided in the course of the inspection. The air quality in the laboratory is tested bi-annually on advice from the contractor and was last monitored in May 2008. The background air quality was assessed as grade C.

Clinical facilities are equipped with emergency equipment including resuscitation equipment: a log was reviewed that showed that the resuscitation equipment is checked daily.

Facilities are provided for staff and include a rest area with basic catering facilities and a supply of drinking water and a changing area and secure storage for personal effects.

Areas for improvement

All offices and consulting rooms are locked at the end of each day, so the records within, are secured. Current patient notes are stored in the nurses' office. On the day of inspection, some patient records were seen in one of the examination rooms. The inspectorate is concerned that there may be a risk that records left in unoccupied rooms could be accessed by non licensed personnel, especially as the unit is easily accessible. This could potentially lead to a breach of S.33 (5) HF&E Act 1990

It is recommended that the PR consider guidance at G.10.2.1 that recommends that the centre should have clear security procedures to prevent unauthorised access to records and to ensure that S.33 of the HF&E Act is not breached.

It was reported that air quality will be monitored every six months. It is recommended that air quality monitoring procedures are validated to provide documented evidence that air quality is maintained in the time intervals between testing (A.10.19).

Areas for consideration

S.6.4.1 requires: where applicable, equipment and materials shall meet the requirements of the relevant EU Directives, 93/42/EC Medical Devices and 98/79/EC In vitro Diagnostic Medical Devices. The PIQ states that all equipment is CE marked. However, on inspection, the CE mark was not seen on the centrifuges, hot blocks and suction equipment. The centre should consider purchasing CE marked equipment and materials to comply with the requirements of S.6.4.1 and seek local advice on the suitability and availability of CE marked equipment.

The counsellor told the inspectorate that the counselling records are held securely and confidentially in a locked metal cabinet at the counsellor's home. It is recommended that the PR reviews security of the records stored in the counsellors home to be satisfied that the arrangements are suitable.

Executive recommendations for Licence Committee

The PR should review:

1. Procedure to comply with requirements of restrictions on disclosure of

information 2. procedures for new purchases of equipment and materials
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
The PR has recently begun to inform his new patients of the risks related to multiple births and has had positive feedback from patients. The centre's information is currently being updated with this development. The Trust has a policy that only nominated persons can seek consent. An audit of patient files, at inspection, showed that patient/donor consents are obtained and completed, documented and stored appropriately (according to HFEA directions (D2006/05), are valid, in date and are provided only after sufficient information has been provided to ensure the consent is informed. The centre deals with potentially contentious WOC cases by discussing any issues at team meetings and referring to the clinician for the final decision. The Trust does not have an ethics committee. Generally, the patient notes were found to be in good order.
Areas for improvement
The outstanding electronic data interface (EDI) errors were discussed in the course of the inspection with the PR and the administrator with responsibility for HFEA form returns. It was reported that efforts to clear the backlog of errors had been hampered by changes to the staff due to promotion, not having a dedicated member of staff responsible for EDI and by lack of (EDI) hardware. The centre has installed a further EDI terminal and this should enable staff to clear the backlog of errors. The PR should review the procedures for submission of information to the HFEA register and ensure that there are no barriers to compliance with Direction D.2008/6.
Areas for consideration
The current licence was not displayed at the time of inspection. The PR to ensure that the latest HFEA Licence only is displayed at the centre.
Executive recommendations for Licence Committee
The PR should ensure:

1. that EDI reporting errors are cleared 2. the latest HFEA Licence only is displayed at the centre
Evaluation
Some improvement required.
Areas not covered on this inspection
Information for service users

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	2.05
Non NMC registered clinical staff	0
HPC registered scientists	4.20
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	4.60
Counsellors	1

Summary of laboratory audit
A summary of the findings of an audit of stored sperm and embryos was submitted prior to the inspection. Minor discrepancies were found in database records and the database was amended. Evidence was provided at inspection that the last audit of stored material was carried out in January 2008 and a copy of the audit of sperm and embryos 2007 was provided pre-inspection.
Summary of spot check of stored material
A spot audit of the stored sperm samples was carried out during the inspection. Two samples were tracked: one from file to tank and the other from tank to file and no discrepancies encountered.
Areas of firm compliance
The PR confirmed that he participates in and keeps up to date with his CPD and

has attended recent conferences relevant to his work. The PR is researching courses for the quality manager to attend and has encouraged all his staff to attend training courses. The PR reported that all new recruits attend the Trust's induction course and that one member of the laboratory team attended CPD training on freezing techniques in the summer. There are plans to send another member of the team to the next course. Online evidence of participation in CPD was seen for one new embryologist.

An audit of donor files completed by the centre shows that donor screening is conducted in compliance with professional body guidelines.

The donor recruitment folder was seen at inspection contained protocols for donor recruitment including, information on donor selection criteria, checklist for donors and procedures for ensuring the 10 family limit is not exceeded. The centre asks for the donor's passport to verify donor identity.

Evidence was seen in the laboratory that processing of gametes and embryos takes place in an environment with specified air quality and cleanliness,. There was evidence that critical equipment is identified and validated, regularly and that new and repaired equipment is tested when installed and validated before use.

The centre participates in inter-laboratory comparisons of sperm assessment parameters through the National External Quality Assessment Service.

Documented procedures are in place to ensure that all gametes and embryos are traceable from procurement to patient treatment or disposal and vice versa. The centre's validation procedures were discussed and record sheets examined at inspection.

There are documented procedures ensuring no activity involving gametes of embryos is carried out without the appropriate consents. The patient notes are sent to the laboratory and patient information is confirmed by staff before any procedure is carried out. Discussions between various staff and the inspectorate confirmed this to be so.

There is an SOP in place to ensure procedures are in place to ensure all gametes and embryos, and data relating to anything contacting them, are traceable from procurement to patient treatment or disposal. Evidence of this was seen in the traceability folder in the laboratory, which also indicated that stock is controlled.

The Counsellor holds the Advanced Diploma in Counselling and is a member of the British Infertility Counseling Association (BICA).

Areas for improvement

The centre could not demonstrate that the competency of each person to perform designated activities has been evaluated at intervals and re-training undertaken when required. This is a breach of Licence condition A.10.11 and

S.6.2.9. The new recruits to the unit reported that they have not been provided with initial or basic training, but the PR told the inspectorate that laboratory staff attend training on new methods of working and practices in this field. An audit of staff training records did not show that procurement of gametes is carried out by trained and competency assessed personnel. This is potentially a breach of A.10.11.

Gametes are transported to another licensed centre in a dry shipper. Evidence or records demonstrating that all appropriate specifications are met before gametes or embryos are released was seen at inspection. The centre's protocol for transferring gametes and/or embryos was reviewed against the requirements of HFEA Alert 21: procedures were not in place to comply with the following recommendations:

1. that the authorised person must be satisfied that the vessel does not contain other samples;
2. that retrieval from storage and packing of samples for transfer is witnessed using patient's unique identifier;
3. the procedure, if labelling on samples has degraded in anyway;
4. the requirements for labelling transport packages (keep upright, biohazard dispatch and destination addresses etc);
5. evidence of controls in place to ensure the person releasing samples to a third party is trained in the procedure.

This protocol should be revised in consideration of the requirements of Alert 21.

Areas for consideration

At the time of freezing, the centre's protocol does not require that witnessing is cross referenced against a unique identifier. G.13.8.2 requires all samples of gametes and embryos to be labelled with at least the patient's/donor's full name and a unique identifier. If at some stages (e.g. labelling donor sperm) it is not possible to label the dishes/tubes with the donor name then it should be ensured that the donor code used is uniquely identifying and the dishes/tubes should be labelled with the female patient's name and unique identifier as soon as possible. The freezing protocol should be revised to ensure that to include a unique identifier to comply with G.13.8.2

On the day of inspection, an audit of storage consents identified that the centre's bring forward system SOP covers only storage of sperm only. This SOP needs be extended to cover embryos to ensure compliance with CoP S.7.8.11 and to prevent a breach of statutory storage regulations and the requirements of schedule 3 of the 1990 HF&E Act.

Executive recommendations for Licence Committee

The PR to ensure:

1. staff competencies to perform designated activities has been evaluated;
2. witnessing protocol is reviewed;
3. procedures to ensure that gametes and embryos are not stored beyond the maximum period as laid down in statute, or the storage period are reviewed.

Evaluation
Some improvement required
Areas not covered on this inspection
All areas covered

Report compiled by:

Name: Bhavna Mehta…….

Designation: Inspector…….

Date: 02/12/08……

Appendix A: Centre staff interviewed

PR and other staff

Appendix B: Licence history for previous 3 years

First Licensed July 1992

2007
Variation of the licence to include the requirements of the EUTD.

2006
Renewal inspection; Licence renewed for 5 years with no additional conditions.

2005
Interim inspection 27th September 2005

Licence Committee 12th January 2005

The Licence Committee agreed to the continuation of the centres licence with no conditions and five recommendations, as follows:

1. The Committee noted paragraph 54 of the inspection report which relates that the centre has carried out three embryo transfers on two occasions to women under 40. The Committee noted that this was a breach of part 8.20 (i) of the Code of Practice. Members therefore agreed that for the next three months the centre be required to submit, on a monthly basis, information detailing how many embryos are transferred. For any three embryo transfers which take place, the centre should detail the age of the patient along with any relevant circumstances. This information will then be used by the Authority to monitor the centre's compliance with section 8.20 of the Code of Practice.

2. The Committee noted paragraph 23 of the report which states that one of the centre's senior embryologists is not registered with the Health Professionals Council. Members agreed that this is a breach of part 1.10 of the Code of Practice and therefore decided to make the recommendation to the centre that this is addressed as soon as possible.

3. The Committee noted paragraph 39 of the report which states that the dewars have not yet been fitted with low nitrogen alarms. Members agreed that if this is not addressed by June this year the centre will be in breach of the directions in chairs letter CH(04)03. Members therefore decided to make the recommendation to the centre that this is addressed as soon as possible.

4. The Committee noted paragraph 74 of the report which states that the inspection team supplied the centre with a list of suggested amendments to its patient information. Members decided to make the recommendation to the centre that it adjusts its patient information accordingly.

5. The Committee noted the findings of the report of a number of errors in patient records, as detailed at paragraph 75. Members therefore decided to make the recommendation to the centre that it reviews its protocols for checking consents prior to treatment."

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0055

Name of PR: Fayez Mustafa

Date of Inspection: 11 November 2008

Date of Response: 20 January 2009

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

Signed:

Name: Fayez Mustafa

Date: 20 January 2009

1. 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).

I am grateful to the PR for pointing out a minor inaccuracy which has now been amended in the report.

Regarding the comment that on the day of inspection some patient records were seen in one of the examination rooms – these notes can only have been the notes of the patient being interviewed by the inspection team. In this instance it was assumed that access to these notes by the inspection team was in order. We can assure you that patient records are never left in unoccupied, unlocked, offices.

With reference to the Non-compliance over a unique identifier at the time of freezing. For both embryo and sperm freezing, a unique identifying 'F number' is used on the sample containers, the paperwork, and on the database. I think the issue stems from the fact that embryo dishes are labelled with full name, a different F number, and dish number. Historically the lab used F (for Freeze) numbers from the very start, while the second type of F number was introduced

with the advent of the database as a couple's unique identifier – the F standing for female. The F for Freeze number and the F for Female number are present in the freeze paperwork and database records for cross-referencing. We do not feel it would be a good idea to start labelling freeze samples with the F for Female number when hundreds of frozen samples already have the F for Freeze number system. This could potentially lead to confusion, and the system as it stands does provide a unique identifier.

Possible typing error –page 19. The paper states that evidence was provided from 2008 Audit of sperm and embryos, and a copy of the audit from 2007 was provided pre inspection questionnaire. However this was the 2008 audit (not 2007).

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

Our organisation chart has been amended as suggested to clearly define accountability and reporting relationships.

There are now only two outstanding errors on the electronic data interface (EDI) system, and a process has been established to reconcile outstanding errors on a weekly basis.

With reference to the average time of 37 days taken to pay HFEA invoices – the electronic ordering and payment system currently utilised by the Trust is in the process of being replaced by a new improved system. When bills are received within our unit they are entered onto the electronic system the same day for payment by the Trust. Unfortunately a lengthy process follows this electronic submission resulting in delays in payment. Hopefully once the new system is in place this delay will be minimised. The new system should be in place within the next three months.

Re the centre using the Trust's incidents and complaints policies, which the inspection team suggests do not reflect the centre's reporting obligation to the HFEA – discussions regarding this are currently ongoing with the Trust's healthcare governance department in relation to the requirements of the HFEA Code of Practice. The inspection team's suggestion of the existence of an appendage to the Trust policies for this purpose is being considered.

Nursing team

The nursing team is developing a competency framework using current RGN guidelines. This will be established over the next six months.

IVF Laboratory.

1. Reference to Competency to perform designated tasks.

A member of lab staff is currently drawing up the paperwork to begin the

competency testing. The start date will be 15 February 2009, and all competencies should be signed off by the start of July. From now on this will be an annual task, and any new members of staff will be tested for competency when they commence their post. All forms will be document controlled as part of the Quality Management System, and records will be kept for the appropriate length of time.

2. Risk Assessments.

The laboratory will carry out risk assessments on witnessing and moving of gametes. This will be completed by June 2009, at the same time as a review of all other IVF laboratory risk assessments.

3. Internal Audit (to determine if QMS satisfies requirements of CoP)

A member of lab staff is currently designing and implementing an internal audit plan for the Laboratory. Guidance has been sought from pathology labs within the hospital, which have an extremely comprehensive internal audit programme. A member of their staff is visiting the lab week commencing 19/01/09. This work is to be undertaken as part of an MSc project. The plan will be developed and implementation started by May 2009. The audit plan will be implemented yearly.

4. Protocol for transferring gametes.

This protocol will be reviewed and updated by the first week of March, in accordance with Alert 21. A member of lab staff has been assigned to this task.

5. CE marking of equipment.

The lab has secured funding for new CE marked hotblocks and suction equipment, these will be purchase as soon as possible. We are currently looking into the availability CE marked centrifuges. Our current centrifuges are in good working order, serviced bi annually, and shown fit for purpose.

6. Systems bring forward SOP for end of embryo storage

Laboratory staff will liaise with the Quality Manager to draw up this SOP. Work completed by end of March 2009.

7. Documented evidence that air quality is monitored (in between scheduled testing)

On the 28th January, at a laboratory meeting a decision will be made to the documented evidence that the lab can provide to show standards are maintained for air quality between the 6 monthly testing (by an accredited lab). The lab will document the measures taken on a weekly basis, members of staff will sign and date a checklist. This will include items such as adherence to dress code, laboratory cleaning and use of filters.

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

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Licence Committee Meeting
11 February 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

Interim Inspection, James Cook University Hospital (0055)

Members of the Committee:	
Anna Carragher, Lay Member (Chair)	Committee Secretary:
Emily Jackson, Lay Member	Claudia Lally
Richard Harries, Lay Member	
William Ledger, Professor of Obstetrics and Gynaecology at the University of Sheffield	Legal Adviser: Stephen Hocking, Beachcroft LLP
	Observers:
Attending via video conference link:	Mair Crouch
Rebekah Dundas, Lay Member	Gemma Hobcraft

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (30 pages)
- one tabled paper: appendix C to the interim inspection report (3 pages).

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and

- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted the report of the interim inspection visit to the centre, which took place on 11 November 2008. The Committee noted that the centre provides a mixture of self-funded and NHS treatments, with a comparatively high proportion of ICSI cycles.

2. The Committee noted the areas for improvement set out in the report. The key areas for improvement were summarised at page six. They were:

- the organisation chart
- payment of invoices
- control of documentation
- provision of training
- witnessing documentation
- the complaints policy and incident reporting policy; and
- the freezing witnessing protocol.

3. The Committee noted the response by the Person Responsible to these issues, which described the work that had been done so far in addressing them. In particular, the Committee noted that:

- the centre had revised the organisational chart as requested
- the centre had put in place a new system for the payment of invoices
- a system is being put in place for competency training for laboratory staff
- the centre's complaints and incidents policies are under consideration, and discussions relating to them are taking place with the Trust's healthcare governance department.

4. The Committee welcomed these developments and asked that all the action taken by the centre in response to the inspection report be followed up at the next inspection. The Committee noted that the Person Responsible's response made no mention of version control of key documents. The Committee agreed, therefore, to highlight the necessity that this issue be addressed. The Committee also noted that the comments made by the Person Responsible about competency training and update training apparently related only to laboratory staff. The Committee decided to remind the Person Responsible that this training should extend to all members of staff.

5. The Committee noted the Person Responsible's remarks that a unique identifier is already used as part of the centre's freezing protocol. The Committee noted that the inspection found that during the witnessing of this procedure, the attribution of this identifier to the sample to be frozen requires to be cross-checked. The Committee endorsed this recommendation and asked that this issue be revisited at the next inspection.

6. On the basis of the inspection report and the response by the Person Responsible, the Committee agreed that the centre's licence should continue with no additional conditions.

Signed……. … Date……..
Anna Carragher (Chair)