Interim Inspection Report

Date of Inspection: 3 August 2010
Length of inspection: 5 hours
Inspectors: Bhavna Mehta; Lynn Nice

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between November 2008 and 22 October 2010

Date of Licence Committee: 20 October 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	The James Cook University Hospital
Centre Number	0055
Licence Number	L0055-15-C
Centre Address	Department of Reproductive Medicine, Marton Road Middlesbrough Cleveland, TS4 3BW United Kingdom
Telephone Number	01642 854 856
Person Responsible	Mr Fayez Mustafa
Licence Holder	Mr Derek Cruickshank
Date Licence issued	1 February 2007
Licence expiry date	31 January 2012
Additional conditions applied to this licence	None

Contents

Page

Centre details 1

Contents 2

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel 3

Details of Inspection findings

Brief description of the centre and its licensing history 4
Activities of the Centre 4
Focus of inspections for 2010-12 5
Changes / improvements since the last inspection 10
Areas of concern 17

Areas of practice that require the attention of the Person Responsible

Critical area of non compliance 18
Major area of non compliance 19
Other area of practice that requires consideration 22

Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspection team considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

The Executive Licensing Panel is asked to note that there are a number of areas of practice that require improvement, including two major areas of non-compliance and one other area of non-compliance. The Inspection team recommends that the Executive Licensing Panel is asked to require that the Person Responsible complies with the following recommendations within the prescribed timeframes set out in the inspection report:

1. The centre has not identified or validated the older equipment still in use at the centre. The identification and validation of equipment must be completed within the timescale given.
2. Evidence of nurses' competencies was not provided at inspection. The transfer of this evidence to the new documentation must be completed within the timescale given.
3. The QMS needs to be developed to meet regulatory requirements and the PR is referred to licence conditions, in particular, to T33 for the documentation which must form part of the QMS which states, at T 33 b, that the QMS must contain "SOPs for all activities authorised by the licence…". This includs, a documented procedure to ensure compliance with the Data Protection legislation and confidentiality requirements under the HF&E Act.

Details of Inspection findings

Brief description of the centre and its licensing history:

The centre is located within the James Cook University Hospital and operates within the South Tees Hospitals Trust. Patients are funded by the NHS or are private patients, referred to the centre for treatment from HFEA licensed centre Cleveland, Centre number 0056 under a satellite arrangement. The centre also has a satellite arrangement to treat patients funded by the NHS, from HFEA licensed centre The Gateshead Fertility Unit, centre number 0170.

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 sperm 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 and has been at the centre since 2006.

Licensing history

First Licensed July 1992
2006
Renewal inspection; Licence renewed for 5 years with no additional conditions.
2008
Interim inspection- the Committee agreed that the centre's licence should continue with no additional conditions.
2009
Variation of Licence to change Licence Holder and to add storage of eggs.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 April 2009 to 31 March 2010*
IVF	110
ICSI	212
DI	8
IUI (2009 data)	13
Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*These data were extracted from the HFEA register for the period 1 April 2009 to 31 March 2010. 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. The live birth rates resulting from IVF /ICSI cycles in all age groups were in line with national averages.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. Private patients are referred to this for treatment under a satellite arrangement with the HFEA licensed centre, Cleveland Gynaecology and Fertility Centre, Centre 0056. The PR stated that no patients have received treatment at this centre since 1 October 2009, so evidence of this theme for inspection was not available. The cost of treatment is discussed with private patients at the time of their gynaecology outpatient appointment and a personalised costed treatment plan discussed and provided at the time of their first consultation at the centre.
What they could do better. None identified at this inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. The lead nurse demonstrated a good understanding of the requirements of consent taking, including consent to disclosure of identifying information to medical or other researchers (so the researchers can contact the patient about specific research projects or carry out non-contact research), consent to storage (including the the12 month 'cooling off' period) and the parenthood provisions. The staff explained that the written consent is obtained from patients/partners and donors before any treatment or donation is provided. The identity of patients and partners is checked by staff and cross checked with documentation at the beginning of each consultation prior to obtaining consent and at each step of the treatment process. The lead fertility nurse explained that she and her team carry out an audit of 20, randomly selected, patient records every six months, requiring all patient records to contain an appropriately and correctly signed consent form prior to treatment or procedures commencing treatment. It was reported that at the last audit, no anomalies were found and no corrective actions required. An audit of patient records, carried out by the inspection team, found that

these records contained the correct consents forms for the treatment to be provided, are signed and correctly filled in.

What they could do better.

Patient records reviewed at inspection included consent to the disclosure of identifying information for use in research. The consent agreed by the patient did not transfer to the HFEA register exactly as given on the consent form signed by the patients'. On discussion, it appeared that the staff at the centre found the language on the HFEA register forms ambiguous. This has been referred to the HFEA Register Department who are looking at clarifying this.

Multiple births

What the centre does well.

The PR reported an overall multiple pregnancy rate at the time of inspection (2009 audit) of 23% (the maximum specified rate in 2009 was 24%).

In compliance with Directions 0003, the PR has provided evidence that the centre maintains a documentary record of their Multiple Births Minimisation Strategy (MBMS) including:

- how the centre identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria
- how the centre aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum specified rate of 20% (the maximum specified rate in for 2010/11).

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy. From 1 March 2009 to 3 August 2010 the centre has carried out two double embryo transfers in patients who met the criteria for single embryo transfer.

Where three embryos or four eggs are transferred the centre has provided detailed record in each patient's records explaining the reason for transfer and provided a summary log in the format laid out in directions (1(a) and (b)

From 1 April 2009 to 3 August 2010, the centre has carried out one three embryo transfers. The patient is over the age of 40 years.

The centre has carried out regular audits and evaluations of the progress and effectiveness of the strategy. Evidence of this was seen in the centres

audit programme and the staff stated that the audits are discussed at team meeting and changes made to the strategy.

The lead embryologist explained at inspection that the MBMS has been revised.

What they could do better.

None identified at this inspection.

Validation of critical equipment and processes

What the centre does well.

All new critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters, these are also identified and appropriately monitored, and the necessary corrective action is taken. The centre has regularly inspected and maintained, in accordance with the manufacturer's instructions, the older critical equipment in use in the laboratory.

At inspection, the critical laboratory processes were seen to have been validated. This validation was based on studies performed by the establishment itself and on data from published studies.

What they could do better.

The centre should identify and validate the older equipment still in use in the laboratory. The centre is encouraged to continue with the planned validation of processes, including the clinical processes and to complete the validation of all critical processing procedures. The centre staff may wish to use the same validation methodology as used in the laboratory.

Witnessing

What the centre does well.

The centre's witnessing practise meets with the regulatory requirements.

The centre staff carry out regular audits of patient records. These are conducted by two members of staff to verify that witnessing checks are recorded. Any errors or omissions are documented and corrective actions taken.

What they could do better.

None identified at this inspection.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well. The payments made to donors are restricted to expenses incurred in the UK and compensation for loss of earnings. The centre reimburses expenses for actual expenses incurred where the donor provides receipts.
What they could do better. None identified at this inspection.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The lead nurse demonstrated a good understanding of the welfare of the child requirements. The PR and staff provided verbal and written evidence that before any woman is provided with any treatment services account is taken of any child born as a result of treatment by the staff at the centre. The counsellor is available for both staff and patients/partners to discuss or further explore any issues that may be raised when considering the welfare of any child born as a result of treatment.
What they could do better. None identified at this inspection.

Embryo testing (if applicable)
What the centre does well. N/A to this centre.

What they could do better.
N/A to this centre.

2. Changes / improvements since the last inspection on 11 November 2008

Area for improvement	Action required	Action taken as evidence during this inspection
The average time taken to pay HFEA invoices is 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.	Action taken. The Finance department at the HFEA has stated that the payments are received within 28 days of the invoice. No further action required.
The lines of responsibility, on the organisational chart submitted with the pre inspection questionnaire (PIQ), were considered unclear for the clinical staff.	The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships. (Standard licence condition A.10.1).	Action taken. The revised organisation chart, showing clear lines of responsibility, was reviewed at inspection. No further action required.
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.	Action taken. The centre's incidents reporting documented procedure meets the requirements of the licence conditions. No further action required.
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.	Action taken. The centre's complaints policy meets the requirements of the licence conditions. No further action required.
Some documents provided with the pre inspection	The PR should ensure that all documents can be uniquely identified	Action taken. A sample of documented procedures

Area for improvement	Action required	Action taken as evidence during this inspection
questionnaire were not uniquely identifiable.	as required by S.5.2.6 and A.10.27.	(laboratory) in the electronic Quality Management System (QMS) was seen to be in line with current requirements. No further action required.
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.	Action taken. The PR has stated that he has ensured that the competence of each person to perform designated activities is evaluated at intervals specified in the QMS and re-training undertaken when required. On inspection, the nurses competencies had not been transferred to the new documentation, so evidence of competencies for the nurses was not seen. Further action required.
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.	Not a requirement in the current CoP.
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	The PR should ensure that procedures are evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards in compliance with S7.8.3.	Action taken. The PR has stated that he has ensured that procedures are evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards in compliance with the Code of Practice.

Area for improvement	Action required	Action taken as evidence during this inspection
witnessing and moving of gametes have not been risk assessed.		No further action required.
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	Action taken. The freezing protocol has been revised to include a unique identifier. No further action required.
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	Action taken. The PR has stated that every possible step is taken to ensure that minutes of departmental meetings give a full record of all the discussions. No further action required.
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.	Action taken. At this inspection, the QMS was demonstrated. However, it is not fully complaint with current requirements and the PR is referred to the standard licence conditions (T32 – T36) to develop it further. Further action required.
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	Action taken. The PR has stated that the centre's protocol for transferring gametes and/or embryos is compliant with the requirements of Alert 21. No further action required.
On the day of inspection, some patient records were seen unattended 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	Action taken. The PR has stated that the centre's procedures to prevent unauthorised access to records have been reviewed by the PR.

Area for improvement	Action required	Action taken as evidence during this inspection
	access to records. G 10 2 1 and S.33 (5) HF&E Act 1990	No further action required.
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.	Action taken. The PR has stated that the equipment seen at inspection that was not CE marked (two centrifuges) is in good working order and is subject to annual testing, validation, and servicing. When this equipment ceases to function, it will then be replaced with equipment bearing the CE mark. No further action required.
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.	Action taken. The PR has stated that there are currently no errors outstanding on the EDI reporting system. The HFEA Register section has reported that six minor errors were outstanding as at 11 June 2010. No further action required.
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.	Action taken. The PR has stated that the centre's bring forward system SOP has now been extended to include sperm and embryos. At inspection the revised standard operating procedure (SOP) appeared to be compliant with current guidance. No further action required.
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	Action taken. The PR has stated that the air quality monitoring procedures are validated by an external organisation every six months, and local measures have been introduced to maintain the quality of the air in the interim period. SOPs have been written to

Area for improvement	Action required	Action taken as evidence during this inspection
	testing (A.10.19).	reflect this. At inspection, the laboratory staff confirmed this. No further action required.
The centre logs incidents and complaints on the Trust's electronic database. 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.	Action taken. The PR has stated that he is to meet with the hospital management to review the logging of incidents and complaints on the Trust's electronic database to ensure that non-licensed personnel are not able to access confidential identifying information. The PR is referred to licence condition T43. Further action required.

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
None		

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Submitting information the HFEA Register: The consent agreed by the patient did not transfer to the HFEA register exactly as given on the consent form signed by the patients'.	Direction 0005 Collecting and recording information for the Human Fertilisation Embryology Authority	The PR is referred to Direction 0005 9(c) to ensure that all registration forms relating to patients undergoing treatment received have been submitted to the Authority and have been filled in accurately.	3 November 2010	An ambiguity exists in the interpretation of "generic consent" on the HFEA consent form and the EDI registration form. Our centre's understanding of "generic consent" clearly differs from that of the HFEA, and some clarity is required. *(This was discussed on the day of inspection and clarification is awaited from*	The HFEA Register team have provided clarification on the CD form. The lead inspector has emailed the PR with this information. No further action required.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
				Inspection Lead.)	
Processing and use of gametes and embryos. The clinical processes and equipment have not been validated. The older (already in use) laboratory equipment has not been validated.	T72	The centre should identify and validate the older equipment still in use at the centre. The centre is encouraged to continue with the planned validation of processes, including the clinical processes and to complete the validation of all critical processing procedures. The centre staff may wish to use the same validation methodology as used in the laboratory.	3 November 2010	The older equipment still in use at the centre will be identified and validated as a matter of urgency. We will continue with the planned validation of processes and will complete the validation of all critical processing procedures.	The identification and validation of equipment must be completed within the timescale given. Action required.
Staff competencies	T15	On inspection, the nurses' competencies had not been transferred to the new documentation, so evidence of competencies for the nurses was not seen.	3 November 2010	The nurse competencies will be transferred to the new documentation as a matter of urgency.	Evidence of nurses competencies was not provided at inspection. The transfer of this evidence to the new documentation must be completed within

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
					the timescale given. Action required.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Data Protection and confidentiality The centre logs incidents and complaints on the Trust's electronic database. The incidents and complaints are investigated centrally in the Trust and feedback provided to the centre. This may lead to a breach of section 33A	section 33A HF&E Act, as amended T43 – T45	The centre must have standard operating procedures (SOPs) to ensure that all information is kept confidential and only disclosed in circumstances permitted by law.	3 November 2010	Agreement has been reached with Trust management that all patient identifiable information will be omitted from any incidents or complaints reported by the centre on the Trust's system. This will ensure that the strict confidentiality provision of Section 33A is not breached. Standard operating procedures will be	The inspection team acknowledge that the agreement with the Trust management will ensure compliance with these requirements. As acknowledged in his response, the PR is required to ensure that the SOP is in place by 3 November 2010. Action required.

because people outside the clinic and therefore, who are not covered by the strict confidentiality provision of section 33A are investigating incidents				documented and added to the QMS detailing how patient information is kept confidential and only disclosed in circumstances permitted by law.	
Quality Management System (QMS)	T32 – T36	To develop the QMS to meet regulatory requirements.	3 November 2010	The QMS plays an integral role in streamlining the patient journey, improving the quality of the service provided, and improving the outcomes for our patients. The evidence of the effectiveness of our QMS development to date is demonstrated by the fact that we have had no reported misses or near	The PR's comments are noted. The inspection team agrees that the centre has made progress since the last inspection in 2008. However, the PR is referred to the licence conditions referenced and in particular to T33 for the documentation which must form part of the QMS which states at T 33 b that the QMS

				misses, and that the results of our recent patient satisfaction survey have proven to be very positive. A comprehensive quality system has been established, a considerable number of SOPs written, as well as the development of a content management system with standardisation of the centre's documentation to include unique identifiers. We have an annual internal audit schedule that includes topics such as laboratory KPIs and pregnancy rates, multiple births minimisation strategy, ICSI performance measures,	must contain "SOPs for all activities authorised by the licence…" Action required.

				traceability of consumables, stored sperm and embryo samples, patient information, and the patient pathway from GP referral to consultant appointment. We utilise the outcomes of our audits as a tool to evaluate our service provision, to monitor and improve our effectiveness. We have established third party agreements with all of our suppliers and review them annually, and we liaise on a regular basis with other UK centres to share good practice. The competence of all our staff is monitored and recorded, and individual training	

				needs are identified under the Trust's Self-Development Review process on an annual basis. All staff attend mandatory fire, health and safety courses annually and bi-annually, and in each area of the centre a member of staff is designated as a health and safety risk assessor. In this way we can ensure the health, safety and welfare of all staff and visitors to the centre. We are currently working on establishing quality objectives and further key performance indicators to monitor and evaluate our processes that will be documented in	

				the quality system and reviewed on a regular basis. We consider the QMS to be a work in progress, we acknowledge the fact that we still have a way to go, but we believe that since our last inspection a considerable amount has been achieved in meeting the regulatory requirements.	

Additional Information from the Person Responsible

After further discussion with my embryology team, I would also like to point out a number of errors in the report and some misinterpretations of the information we provided.

1) Focus of the Inspection

a) Multiple births

Report states that the MBR from 2009 audit was 23%. Actual: For 2009 the ongoing MBR is 15.1% (we do not have all the live birth results yet). The 23% relates to the period March 2009- April 2010, for which the clinical MBR is 23.8%.

Report states that from 1 April 2009 to 3 August 2010, the centre has carried out 1 transfer in whom 3 embryos were replaced (3 ET) and the patient was over 40. Actual: For this period the centre has carried out 15 x 3 ET in patients over 40, and 2 x 3 ET in patients under 40 years. *[A form was given to Lynn Nice listing the patients under 40 who have had 3 embryos transferred. Only 1 patient was listed on this form, (which was a mistake as we have performed 2, the second patient has now been added to the Log). I think this is where the confusion has arisen from].* The centre now has a form to record all patients who have had 3 embryos replaced, as stated in the Code of Practice.

Report states that the MBR rate strategy is discussed at team meetings and changes made to the strategy. Actual: The MBR strategy has been discussed at team meetings; however no changes have been made to the strategy since the introduction in March 2009.

Report states that the lead embryologist explained at inspection that the MBMS has been revised. Actual: The embryologists explained that regular audits have been completed on the MBMS. Again however, the strategy has not been revised.

b) Witnessing

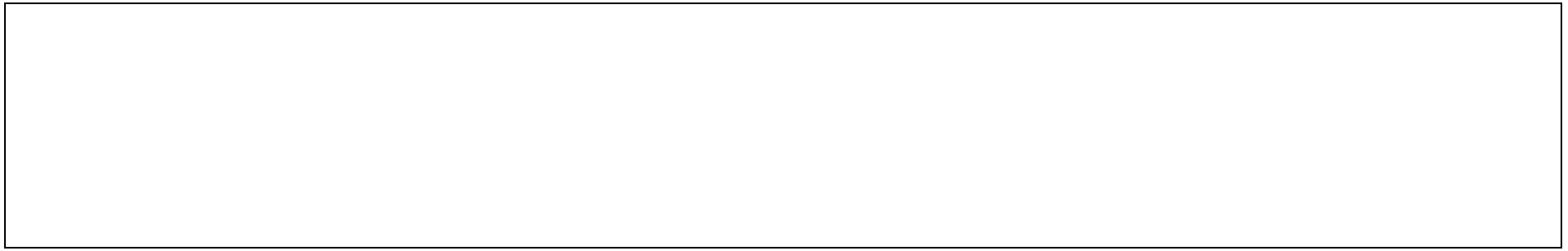
The report states that there are regular audits of patients records to check witnessing records, and that two members of staff verify the witnessing checks at audit. Actual: Regular witnessing audits are performed; however only one person conducts the audit to check that witnessing document is signed by 2 members of staff.

2) <u>Major Area of non-compliance</u>

a) Data protection and confidentiality

The report states that incidents and complaints are reported centrally within the trust and feedback is given, which may breach section 33A. Actual: No identifying information is added to the trusts incident reporting system (DATIX), and therefore when reporting incidents confidentiality is not breached. This is stated in 'OPERATING PROCEDURE No. 6' of the Quality Manual. For complaints; if the complaint cannot be resolved in house (as described in OPERATING PROCEDURE No. 6' of the Quality Manual), the patient(s) are advised to contact either the Patient Advice and Listening Service (PALS) or the Patient Relations Manager within the Trust. We do not pass this information on to the PALS team or Patient Relations Manager, and are therefore not breaching confidentiality. The patient would contact the appropriate group / person, thereby consenting for their complaint to be investigated.

Finally the report fails to mention the lack of continual alarm monitoring for the Incubators.



HFEA Executive Licence Panel Meeting

20 October 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 5

Centre 0055 (The James Cook University Hospital) - Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine Observing: Claudia Lally, Compliance Business Support

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The centre's first licence was granted in 1992. It has a good history of regulatory compliance and the current licence, active until 31 January 2012, has no additional conditions placed upon it.

2. The Panel noted that the centre is predominantly NHS, however, private patients are also transferred from centre 0056 (Cleveland) under a satellite agreement.

3. The Panel noted that the centre also has a satellite agreement in place to treat NHS funded patients with centre 0170 (The Gateshead Fertility Unit).

4. The Panel considered the Interim Inspection Report and was satisfied that the centre was broadly compliant. The Panel noted that there were some areas of non-compliance highlighted within the report. However, it was satisfied that the PR has committed to implement all remaining recommendations within the required deadlines.

5. The Panel agreed that since the previous inspection in 2008, there is good evidence of compliance.

Decision

6. The Panel agreed to the continuation of the centre's licence without any conditions placed upon it. The Panel endorsed the Inspectorate's recommendations and associated timeframes for the PR to meet these recommendations.

Signed: Peter Thompson Date: 2/11/2010.

Peter Thompson (Chair)