Renewal Inspection Report

Assisted Reproduction Unit
University Hospital of Hartlepool
0031

Date of Inspection: 29 September 2009
Date of Licence Committee: 3 December 2009

Centre Details

Person Responsible	Dr Iona MacLeod
Nominal Licensee	Ms Susan Blowers
Centre name	Assisted Reproduction Unit ARU
Centre number	0031
Centre address	University Hospital of Hartlepool Holdforth Rd Hartlepool TS249AH
Type of inspection	Renewal Inspection
Inspector(s)	Paula Nolan (Chair HFEA Executive) Angela Sutherland (HFEA Executive) Victoria Lamb (HFEA Executive) Miriam Glenn (HFEA Executive observing)
Fee paid	Renewal fee paid
Licence expiry date	28 February 2010

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About the Inspection:

This inspection visit was carried out on 29 September 2009.

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 what needs to be addressed but not how 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 www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Hartlepool Assisted Reproductive Unit has been licensed since 1992 and has a good history of compliance with no previous conditions on its licence. Centre 0031 has completely renovated their premises although no changes have been made to laboratory or storage facilities. A range of licensed treatments are offered to both private and NHS funded patients, most of the referrals being from Hartlepool and the surrounding areas.

Activity has increased from 102 cycles in 2007/08 to 143 cycles in the period between 2008/09.

The Person Responsible (PR) has completed the HFEA Person Responsible Entry Programme. She is registered with the General Medical Council (GMC) and is on the Obstetric and Gynaecology specialist register.

Activities of the Centre[1] for the time period from June 2008 to May 2009 (number of cycles)

In vitro fertilisation (IVF)	66
Intracytoplasmic sperm injection (ICSI)	66
Frozen embryo transfer (FET)	5
Donor Insemination (DI)	6
Research	n/a
Storage gametes/embryos	Yes

Summary for Licence Committee

This report documents the evaluation the centre's compliance with the requirements of the 7th Code of Practice which was in force at the time of the inspection. On 1 October 2009 the 8th Code of Practice, amended legislation and revised statutory licence conditions came into force. To accommodate this transition, the centre's compliance at the time of the inspection is referenced to the 7th COP while recommendations for improvement are referenced to the 8th COP.

In considering overall compliance the PR is considered to have discharged her duties satisfactorily under S.17 of the HFE Act. Some improvements are recommended in relation to payment of fees.

Premises and equipment were considered generally suitable. Some improvements are recommended in relation to validation of the frequency in which air quality is monitored.

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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.

The centres practices were considered suitable. Some improvements are recommended in relation to document control and patient information.

Based on the evidence seen on inspection the inspectorate concluded that no improvements, with relation to the requirements of the Code of Practice, are required in the areas of laboratory and clinical practice.

The inspection team supports the renewal of the centre's licence for a period of four years subject to compliance with the recommendations within the prescribed timeframes.

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
For the year from 1 April 2009 to 27 August 2009 the centre took an average 33 days to pay invoices. This was a breach of standard licence condition A.13.3 of the Code of Practice (7th Edition). **This breach was noted on the previous inspection.**	The PR should review and consider whether there are barriers to the prompt payment of HFEA invoices.	Immediately. To be monitored at next inspection.
At inspection several documents were found that had not been reviewed and/or updated within a 12 month period. This was a breach of S.5.2.5 of the Code of Practice (7th Edition) **This breach was noted on the last**	The PR should give consideration to the guidelines provided at 36.1 of the 8th Code of Practice that all documents should be reviewed, revised and reapproved at a frequency	To be completed by 29 December 2009.

inspection.	that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.	
Progress has been made with the validation of laboratory processes but some validations remain outstanding. Validation of air quality monitoring has not been completed. This was non compliant with the requirements of standard licence conditions A.10.13 and A.11.11 of the Code of Practice (7th Edition). **Validation was a breach noted on the last inspection.**	In compliance with T24 and T72 of the 8th Code of Practice, the PR should ensure that procedures for air quality monitoring must be validated. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well established processing procedures.	To be completed by 29 December 2009.
In the course of the consent audit an anomaly was found in one set of patient records.	The PR should establish quality indicators relevant to the taking and establishment of consent and audit practice against compliance with the approved protocols, the regulatory requirements and quality indicators. (T35 and T36 8th Code of Practice).	The audit should be completed by 29 December 2009. The findings and corrective actions must be documented. The HFEA should be advised when the audit is compete.

Non-Compliance

Area for improvement	Action required	Time scale
Patient information does not include information on waiting times (G.5.3.1.b) and the consequences of withdrawal of consent (G.5.2.1.d). Information for those seeking treatment with donated gametes does not include relevant information on the likelihood of inheritance of	The PR should review the patient information against the requirements of the 8TH Code of Practice.	At the PR's discretion. To be monitored at next inspection.

physical characteristics (G.5.4.1.b) or information on screening tests that donors undergo (BFS and BAS guidelines) (G.5.4.2).		

Recommendations

Area for improvement	Action required	Time scale
n/a	n/a	n/a

Changes/ improvements since last inspection

Recommendations	Action taken since previous inspection
For the year from June 2007 to July 2008 the centre took an average 32 days to pay invoices. This is a breach of standard licence condition A.13.3 of the Code of Practice.	Following the last inspection the PR advised the HFEA that invoices were being sent to the NL who is based at a different Trust site and this was delaying prompt payment of invoices. The PR has requested that invoices are sent directly to the Trust's finance department to ensure prompt payment. **At present the time taken to pay invoices is 33 days in breach of A.13.3.**
The centre does not have a quality management system that was considered by the inspectorate to be compliant with CoP S.5.1.1.	Following the last inspection the PR advised the HFEA that further work had been carried out on the quality management system and evidence of this was seen at inspection.
While an organisational chart was provided at inspection, the centre currently does not have a quality manual that adequately reflects the requirements of CoP S.5.2.4.	Following the last inspection the PR advised the HFEA that further work had been carried out on the quality manual and this was evident on inspection.
The quality manager reported that a patient questionnaire had been devised but this did not appear to be in permanent use and it's results were not analysed.	Following the last inspection the PR advised the HFEA that a patient satisfaction questionnaire has been developed. This survey and the follow up action plan were made available to the inspectorate.
At inspection several documents were found that had not been reviewed and/or updated within a 12 month period.	Following the last inspection the PR advised the HFEA that all documents have been updated. However, on the current inspection some of the documents had not been reviewed in the last 12 months
Interviews with nursing staff and the QM at	Following the last inspection the PR advised

inspection revealed that nursing staff training and competency assessment is not being adequately reviewed or documented. Inspection of nursing staff training folders provided at inspection contained no evidence of initial or annual competency assessment and sign off of critical skills.	the HFEA that a competency assessment programme for nurses would be developed and implemented. Competency assessments for both clinical and embryology staff were made available to the inspectorate and were considered appropriate.
It was found at inspection that laboratory processes have not been validated.	Following the last inspection the PR advised the HFEA that progress had been made on the validation of laboratory processes and that the results would be available on the day of inspection. Air quality testing had not been validated at the time of the inspection however.
Since last inspection three, three embryo transfers have taken place in women under the age of 40.	Following the last inspection the PR advised the HFEA that no three embryo transfers have taken place in women under the age of 40. The PR supplied a copy of the three embryo transfer log confirming that no three embryo transfers had taken in women under the age of 40.
Discussion with the ARU quality manager confirmed that while clinical governance is part of her role, to date she has been unable to dedicate more than minimal time to clinical governance and/or quality management. Currently these responsibilities are largely managed by an individual employed by the trusts maternity unit, with no formal, dedicated WTE allocated to ARU. Discussion with the Clinical Governance Manager confirmed that if (as is expected) her workload within the maternity department increases she is unlikely to be able to continue dedicating the same level of commitment to ARU.	At inspection the quality manager explained that she has two days dedicated to her role and that the trust's clinical governance manager now has less input into clinical governance and/or quality management responsibilities.
Inspection of meeting minutes suggested that the PR has been absent from approximately two thirds of the centre's multi disciplinary meetings.	On inspection a review of the meeting minutes confirmed that the PR had attended most of the multi-disciplinary meetings.
At inspection it was noted that there is some distance to travel between the laboratory and new cryostore room, down a corridor that is at times busy with pedestrian traffic, causing a potential hazard.	Following the last inspection the PR advised the HFEA that a risk assessment had taken place and she was satisfied with the procedure. A copy of the risk assessment was supplied with the pre inspection questionnaire. On inspection the scientific inspector was satisfied with the arrangements.
During the tour of the centre's new premises	Following the last inspection the PR advised

it was noted that non-licenced maternity unit staff are able to gain direct access to ARU via an unlockable door in the shared staff room.	the HFEA that a coded key lock has been fitted to the door. This was confirmed during the tour of the centre on inspection.

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
Leadership and management Documentation submitted for inspection, including an organisational chart showing key responsibilities and lines of accountability was reviewed by the inspection team and is considered to be appropriate. **Organisation of the centre** During interview on the day of inspection the PR and senior staff confirmed that all members of staff are appropriately qualified and experienced for their roles. This was confirmed by review of staff curriculum vitae and training logs supplied at inspection. Staff interviewed during the inspection confirmed that they are encouraged to make suggestions and are kept up-to-date of changes and developments within the centre. **Resource management** The premises appeared suitably equipped and the PR reported that she is confident that the unit has sufficient staff with relevant expertise. **Clinical governance: Incident and complaints management** At inspection a comprehensive log was supplied that documented the system used to manage and resolve complaints and incidents. Complaints information was clearly displayed in the patient waiting area in compliance with CoP S.9.2.2. There were no significant incidents in the centre log that had not been reported to the HFEA and all incidents appeared to have been resolved appropriately. **Third party agreements**

The PR reported that all third party agreements have been established in compliance with standard licence condition A.5.1. All agreements were provided at inspection and a sample of these examined appeared compliant with requirements.

Risk management
At inspection a comprehensive record was observed containing 19 up-to-date risk assessments, across all specialties. Discussion with the quality manager confirmed that all staff are involved in the assessment of risk at the centre and appropriate tools are available to all.

Contingency arrangements
The inspectorate saw a written contingency arrangement with the North East Fertility Forum. The PR was able to verbally describe contingency arrangements to cover unexpected staff absence across all specialities.

Meetings/dissemination of information
Multi-disciplinary meeting records were reviewed in the course of the inspection. The meetings appear to be regular and well attended with clear communicative minutes.

Areas for improvement

For the year from 1 April 2009 to 27 August 2009 the centre took an average 33 days to pay invoices. At the time of the inspection this was in a breach of standard licence condition A.13.3 of. The PR explained that steps were being taken to rectify the problem.

Areas for consideration

None.

Executive recommendations for Licence Committee

None.

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 the time period from 1 January 2005 to 31 December 2007 the centre's outcomes were in line with national averages for IVF/ICSI and FET.
Areas of firm compliance
Quality management system/manual The centre has a quality management system and manual in place that was found at inspection to include documented procedures as required by the HFEA CoP. **Quality policy** A quality policy has been developed that is available to all staff: the document was reviewed in the course of the inspection and was found to be compliant with all aspects of CoP S.4.2. It was noted that a signed version of the policy was also displayed in the centre's main waiting room. **Quality objectives and plans/review** The quality manager explained that the current quality management system has been in place for less than a year and she intends to review the system on an annual basis. Measurable quality objectives were defined in the manual as: • Reports on the effectiveness of the systems in place by the quality manager • Success rates • Feedback from patient questionnaires **Feedback** A patient suggestion box is available in the waiting room. A patient satisfaction survey was carried out in 2008 and 2009. An action plan was drawn up following analysis of the 2009 patient feedback and was made available to the inspectorate on the day of inspection. The centre also holds a monthly patient forum and encourages informal feedback at this event. The PR explained that staff are encouraged to provide feedback via multidisciplinary team meetings.
Areas for improvement

Document control At inspection several documents including the serious adverse events policy, complaints policy, risk policy, witnessing and tractability sops were found not to have been reviewed and/or updated within a 12 month period. At the time of the inspection this was non complaint with the requirements of S.5.2.5 of the 7th CoP and remains non compliant with guidance provided at 31.6 of the 8th CoP.
Areas for consideration
None.
Executive recommendations for Licence Committee
The PR should consider guidance provided at 31.6 of the 8th CoP which recommends that documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.
Evaluation
Some 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

Premises

At the time of inspection these facilities were noted to be spacious and well organised with a logical activity flow and good access to the area where licensed activity takes place.

Clinical facilities

The inspectorate were satisfied that the clinical facilities including the sperm production room ensure that patient privacy and dignity is maintained. The emergency trolley outside the recovery area was checked and found to be well maintained. It is checked on a daily basis and entries were seen to be made in an appropriate log.

Counselling facilities

Counselling is provided in quiet, comfortable and private facilities.

Laboratory facilities

Discussion with staff and observation during the inspection showed that laboratory facilities appear to be appropriate for licensed activities carried out in them. Servicing and maintenance records were complete for all pieces of equipment inspected. Storage dewars were fitted with the appropriate alarms and procedures for responding to emergencies are in place. Inspection of the laboratory confirmed the presence of a low O_2 monitor and extraction fans.

Air quality

Air quality is assessed twice a year by an external contractor. At inspection records were seen of air quality results that demonstrated compliance with CoP A.10.21.

Management of equipment and materials

The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment.

Storage facilities for gametes and embryos

The premises are secure and each dewar is fitted with low nitrogen level monitor. The room contains a low O_2 monitor in compliance with CoP S.6.4.2.

Storage of records
A tour of the premises and discussion with the quality manager and PR confirmed that all current clinical records are stored in a dedicated locked room, inside locked cabinets only accessible by licensed staff in compliance with CoP S.7.2.1.

Areas for improvement

While inspection revealed compliance with the validation of key equipment, validation of air quality monitoring has not been completed. This was non compliant with the requirements of standard licence conditions A.10.13 and A.11.11 of the Code of Practice (7th Edition).

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR should ensure that procedures for air quality monitoring must be validated in compliance with the requirements of T24 and T72 of the 8th Code of Practice. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well established processing procedures. Validation should be completed by 29 December 2009. Confirmation of completion of this validation should be provided to the HFEA.

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
Consent The quality manager reported at inspection that patient consent is taken only by herself or the treating consultant. An audit of consent in five sets of randomly selected patient records found that consents were present and compatible with the treatment provided in four of the five sets of records. **Welfare of the Child** Both the PR and quality manager informed the inspectorate that the unit has a robust system for multidisciplinary discussion and process for escalation of potential welfare of child issues. The WOC forms were properly completed in all five sets of patient records randomly audited at inspection. **Access to health records** The quality manager/senior nurse has designated responsibility for the management of requests for access to patient records in compliance with CoP S.7.2.2. **Provision of information to the HFEA register** There were no reported problems relating to reporting from the Registry Department of the HFEA.
Areas for improvement
In the course of the consent audit an anomaly was found in one set of patient records: although the female patient consented to store her embryos she had not indicated whether she wanted her embryos to continue in storage in the event of mental incapacity or death. The quality manager explained that she would ensure the consent form was completed correctly.
Areas for consideration
Patient information does not include information on waiting times (G.5.3.1.b) and the consequences of withdrawal of consent (G.5.2.1.d). Information for those seeking treatment with donated gametes does not include relevant information on the likelihood of inheritance of physical characteristics (G.5.4.1.b) or information on screening tests that donors undergo (BFS and BAS guidelines) (G.5.4.2).

Executive recommendations for Licence Committee
The PR should review the patient information in consideration of the 8th Code of Practice guidelines. The PR should establish quality indicators relevant to the taking and establishment of consent and audit practice against compliance with the approved protocols, the regulatory requirements and quality indicators. The audit should be completed by 29 December 2009: findings and corrective actions must be documented. The HFEA should be advised when the audit is compete (T35 and T36 8th CoP).
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

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
  - 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	3
NMC registered nurses	4
Non NMC registered clinical staff	1
HPC registered scientists	2
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	3
Counsellors	1

Summary of laboratory audit
A summary report of the laboratory audit of cryopreserved material was provided with the pre inspection questionnaire. Results of the embryo audit and sperm tanks audit carried out in June 2009 showed no discrepancies.
Areas of firm compliance
Staff training and competency An induction programme is in place for all staff. Documentation of comprehensive competency assessments for both clinical and embryology staff was made available to the inspectorate and considered appropriate. **Three embryo transfer** The three embryo transfer log provided evidence that no three embryo transfers had been conducted on women under the age of 40. **Procurement, distribution and receipt of gametes and embryos** There are documented procedures for procurement, packaging, distribution, recall and receipt of gametes and embryos that ensure: quality and safety of the gametes; risk of contamination is minimised; evaluation, assessment and safety of the provider and that procurement

conforms with appropriate age limits for gamete providers.

Traceability and coding
During the inspection evidence was provided that materials and equipment which comes into contact with gametes and embryos are traceable from procurement to disposal.

Selection and validation of laboratory procedures
Inspection revealed that good progress has been made with the validation of laboratory processes.

Coding /identification of samples/Witnessing
Laboratory staff explained and demonstrated that the centre's witnessing protocols ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process in order to prevent mismatches of gametes or embryos at any point of the laboratory or treatment process.

Counselling Practice
The centre's counsellor is appropriately qualified and undertakes regular professional supervision. When asked, the counsellor was able to describe good communication with the centre team and evidence of attendance at unit meetings was seen.

Counselling audit
An audit of the counselling service provided in 2009 has been carried out. A copy of the report resulting from this audit was provided to the inspection team. In total 35 referrals were made with 71 counselling sessions delivered for 110 treatment cycles.

Storage of gametes and embryos
There was seen to be a protocol and procedure in place to ensure that gametes and embryos are not stored beyond the maximum period consented for by patients or by statute.

Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

Report compiled by:

Name: Paula Nolan

Designation: Inspector

Date: 28 October 2009

Appendix A: Centre staff interviewed

PR: Dr Iona MacLeod, quality manager/specialist nurse, a nurse, senior embryologist, principal embryologist, counsellor.

Appendix B: Licence history for previous 3 years

Type	Active From	Expiry Date
Treatment with Storage	01/12/2005	28/02/2007
Replaced by New Version	05/07/2007	28/02/2010
Replaced by New Version	01/03/2007	28/02/2010
Replaced by New Version		28/02/2007
Replaced by New Version	01/03/2004	28/02/2007

28.01.08 Change of PR

The basis of the information before them the Committee approved the centre's application for Dr Macleod to be Person Responsible for the centre.

26.04.07 EUTD Variation

The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……031……

Name of PR……Dr Iona Macleod……

Date of
Inspection…29/09/2009……..

Date of
Response…16/11/2009……

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

Signed……

Name ……Iona Macleod……

Date……16/11/09……
……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

The one set of notes found by the HFEA with a consent anomaly was a "consent for storage" with the Posthumous consent not signed. However, no embryos or sperm were frozen for storage in the course of this treatment cycle.

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

Average 33 days to pay invoices; We have tried to rectify this problem on several occasions by informing the HFEA to whom they should send the invoices for prompt payment. On further discussion with Paula Nolan, the HFEA finance department has been contacted to ensure invoices go directly to the Trust's finance department. The problem should now be rectified.

Documents found not to have been reviewed within a 12 month period

These were trust documents in line with The Trusts risk management standards. The Trust has a policy for 3 yearly development and ratification of documents and would like to continue with that. Our unit will look at these documents yearly. All ARU documents were reviewed yearly.

Validation of air quality

After last HFEA inspection it was suggested by the HFEA inspector that we should validate our air quality by increasing the number of air quality tests to 2 per year and to put settle plates down every month. This was organised and presented to the HFEA at inspection. Further to our recent inspection, it is now our intention to check air quality initially, daily, then weekly, then monthly.

Audit Consents

10 sets of notes to be audited for anomalies. This will be started in December 2009.

Patient information does not include waiting times, the consequences of withdrawal of consent information on inheritance characteristics and screening tests that donors undergo.
(G5.3.1.b)(G5.2.1.d)(G5.4.1.b)(G5.4.2)

Our information sheets will be reviewed in the near future and altered to include the above information.

HFEA Executive Licensing Panel Meeting

3 December 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Hartlepool General Hospital (0031), Licence Renewal

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Ian Peacock, Analyst Programmer	Committee Administrator: Joanne McAlpine

Declarations of Interest: members of the Panel 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 (42 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers for this item: the renewal inspection report, an application for renewal of licence and the last three years of previous Licence Committee minutes.

2. The Panel noted that the centre's inspection took place on the 29 September 2009 before the amended legislation and revised statutory licence conditions came into force on the 1 October 2009. The Panel therefore recognised that the centre had been inspected against the 7th Code of Practice, however recommendations made by the inspectorate are referenced to the 8th Code of Practice.

3. The Panel noted the breaches within the inspection report on pages 6 and 7 with the relevant timescales and endorsed the inspectorate's recommendations.

4. The Panel noted the Person Responsible's informative response on page 22 and 23 of the inspection report and concluded that the outstanding areas for improvement had now been or were being adequately addressed.

5. The Panel noted that Dr Iona MacLeod has completed the PR Entry Programme and noted that there are no issues regarding the character, qualifications or experience or ability to discharge the necessary duties under section 17 of the HFE Act 1990 (as amended). On the basis of the information provided, the Panel agreed that it was satisfied of the suitability of the Person Responsible and the premises.

6. The Panel agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination, and was in receipt of a signed application form and the relevant fee had been paid.

7. The Panel noted that there is a quality management system in place and that there is evidence to suggest that the centre has complied with the criteria in accordance with the guidance on periods for which licences should be renewed and granted.

8. The Panel note that this centre is generally compliant, but that there are still areas for improvement highlighted within the report and would endorse the inspectorate's recommendations.

<u>The Panel's Decision</u>

9. The Panel agreed that the licence should be renewed for a period of 4 years with no additional conditions, subject to the outstanding recommendations being complied with within the relevant timescales. Evidence to support this should be supplied to the executive.

Signed..... Date.....

Peter Thompson (Chair)