Renewal Inspection Report

The Hull IVF Unit
0021

Date of Inspection: 4 March 2008
Date of Licence Committee: 7 July 2008

CENTRE DETAILS

Centre Name	The Hull IVF Unit
Centre Number	0021
Licence Number	L0021-11-a
Centre Address	Woman and Children's Hospital, Anlaby Road, Hull HU3 2JZ
Telephone Number	01482 382648
Type of Inspection	Renewal
Person Responsible	Mr Steve Maguiness
Nominal Licensee	Mr John Robinson
Inspector(s)	Janet Kirkland (HFEA Lead inspector)
	Dr Vicki Lamb (HFEA Scientific inspector)
	Elizabeth Orton (HFEA inspector observing)
Fee Paid – up-to-date	Not Due - Interim
Licence expiry date	30 September 2008
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on 4th March 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between June 2005 and March 2008.

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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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 Hull IVF Centre has been licensed since 1986 and offers treatment to both NHS and private patients.

The Centre is custom built and located within the Hull and East Yorkshire (HEY) Women and Children's Hospital and therefore benefits from facilities offered by the hospital including:

- Pharmaceutical services
- Resuscitation services
- Infection control
- Maintenance
- Laundry services
- Clinical governance arrangements

The Person Responsible (PR) is a Consultant Obstetrician and Gynaecologist and has been in post since the inception of the Centre. He has completed the PR entry programme which was assessed as being satisfactory.

Activities of the Centre

Licensed treatment cycles	327
Donor Insemination	0
Unlicensed treatments	Ovulation induction
Research	✗
Storage	✓

Summary for Licence Committee

The Hull IVF Centre has been licensed since 1986 and offers treatment to both NHS and private patients. The Centre was granted an HFEA inspection holiday in 2006, but subject to an unannounced inspection during that year.

Patient areas were considered by the inspection team to be well presented.

The nurses at the Centre perform the following:

- Administration of Intravenous sedation
- Embryo transfers
- Nurse consultations
- Intrauterine insemination
- On call cover

In addition the senior nurse performs vaginal oocyte collections.

All members of the team interviewed on inspection expressed satisfaction with the level of

support from the Person Responsible and opportunities for Continuing Professional Development.

Patient feedback at inspection and through patient questionnaires returned to the HFEA was primarily complimentary of the Centre team and treatments offered.

The inspection team recommend renewal of the Centre's licence for a period of five years.

Risk Assessment

The risk assessment performed after the inspection was 0%.

Evaluations from the inspection

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

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
None		

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
None	

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

Recommendations	Action Taken
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 findings from inspection
Evidence is drawn from:

1. Leadership and management
2. Organisation of the Centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
The Centre was considered by the inspection team to be well organised. The PR, whilst not in the Centre every day, is present in the main hospital and informed the inspection team that he can be contacted at any time. An organisational chart was seen to be in place with clear lines of reporting. Staff interviewed considered that the Centre was adequately resourced. The PR informed the inspection team that they are expecting an increase in the number of patients who are funded by the National Health Service. They could, in his opinion, accommodate up to 400 treatment cycles per year. In response to this increase their business plan includes recruiting a further embryologist. In addition a nurse is currently undergoing an induction programme. Risk is assessed as part of each Standard Operating Procedure (SOP), to assess the process and control measures in relation to staff/patients/premises/procedure inherent risk. They have external occupational health advisors/auditors. The Charge Nurse is the designated Health and Safety Officer (H&S) and reports to the HEY Trust H&S advisor. Risk assessments performed in the previous twelve months include: • Annual review / update of Control of Substances Hazardous to Health (COSHH) forms. • Risk assessment of premises • Pregnant staff - working conditions The Nominal Licensee is the designated individual in charge of incidents. All staff interviewed on the day of the inspection were aware of the incident reporting procedure for both the Trust and the HFEA. The incident folder was seen by the inspection team. Details of incidents had been

appropriately documented and complied with HFEA requirements.

In the event that the service is terminated unexpectedly a third party agreement / contingency arrangements is in place with Care Sheffield (Centre 0061). There is, in addition, a service level agreement with Hull and East Yorkshire Trust regarding alternative facilities.

The PR informed the inspection team that a clearly defined Clinical Governance structure is in place.

There are no issues reported with regards to payment of treatment fees to the HFEA.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvement required

2. Quality of service

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

Summary of findings from inspection:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
The HFEA held register data* (31 March 2002-1st April 2005) show: • ICSI/IVF success rates are in line with the national average • Frozen embryo transfer success rate are in line with national average • Donor insemination success rates are in line with national average. *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 on our website 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.
Areas of firm compliance
The Centre has an in house developed Quality Management Programme. The laboratory manager is also the Quality Manager. The Centre has an extensive range of SOPs and protocols developed following discussion with staff and approved by the Senior Management Advisory Group (SMAG). They are: • reviewed and updated regularly and changes are approved by SMAG • version controlled and staff sign to say they have seen the protocol and any changes made • individually risk assessed • audited as part of the annual audit cycle to ensure compliance Files seen by the inspection team included: • Quality reviews, Total Quality Management minutes up to November 2007 and a QM

staff survey to see if they understood the QM system

- Quality audit 2008 – a comprehensive framework document
- Nursing audit – audit of nursing activity for 2007
- Complaints - A complaints procedure is in place and the Nominal Licensee is the designated complaints officer. Seven complaints had been received since the previous inspection, all of which had been resolved. The complaints folder was seen by the inspection team. Responses were seen to letters of complaint.

Information on display in the patient waiting area included a notice explaining how to make a complaint and treatment results.

Every patient attending the Centre is asked to complete a patient satisfaction survey which is returned anonymously. The results are audited monthly and discussed at the SMAG group. The minutes of the meeting reflect any actions required for feedback to each division.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
No improvement required

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
There have been no changes to the premises since the previous inspection. The Centre is located within the Women and Children's Hospital. The hospital is a relatively new building (5 years old) and the IVF Centre is on the ground floor – accessed via the main hospital reception. Entry to the Centre is through a set of security controlled doors. The Centre is self contained (apart from the cryogenic store which is just outside the entrance to the Centre). The treatment/consulting rooms are located in one corridor leading off the waiting room through security controlled doors. The Centre's facilities include: • A disabled toilet • Two consulting rooms which were seen to be private, clean and tidy • Two scan rooms • Treatment room • Staff changing room • Four bedded 'ward' used for embryo transfers and as a recovery bay • A men's room with a toilet, hand basin, chair , alarm cord and security controlled entrance • A room used for patient group sessions • A staff meeting room with a notice board displaying the organisational chart, a 2007 key performance indicator graph and details of a continuing professional development seminar. An emergency trolley was seen to be in place in the recovery area with a signed audit sheet showing that it was checked on each treatment day. Counselling sessions are conducted at a location away from the Centre. The counsellor informed the inspection team that counselling notes were stored securely at her home. The laboratory was seen to be spacious and well equipped

The pre inspection questionnaire (PIQ) stated that the following equipment had been purchased since the previous inspection:

- Facilities Monitoring System
- IVF Witness System (RFID tag technology)
- Class 1, flow hoods x 2 (for ICSI lab)

Documents seen on inspection by the scientific inspector included:

- Air quality records for October 2007 - all had passed
- Daily records of temperature and carbon dioxide levels for the incubators
- A record of calibration of the carbon dioxide alarms for January 2008
- Risk assessments for the laboratory
- Equipment maintenance log
- Calibration certificates for incubators within the flow hoods
- Service records for some items of equipment
- Cleaning records

The laboratory manager explained that all equipment is serviced and third party agreements are in place.

Validation: Data was seen on inspection which was to be written into a report. It was in draft form for most processes. The scientific inspector was informed that some equipment is validated by the suppliers.

CE marked equipment is used where available.

The cryostore is situated opposite the Centre's entrance, in a main corridor. A CCTV camera was seen to be in place which links to the reception area, although it was not on at the time of the inspection.

In view of the cryolab's position the procedure for transporting gametes/embryos from the cryolab to the treatment areas involves two members of staff: one to carry the sample and another to ensure that the way is clear.

Low liquid nitrogen alarms were seen to be on all tanks and attached to an autodialler. In the event that the alarms are activated the autodialler rings the main hospital switchboard which in turn contacts the on call embryologist.

Staff facilities include:

- A small kitchen area

- A staff meeting room
- Changing facilities

Records of patients currently going through treatment were seen to be stored in locked cabinets within a room which is locked when not in use. Archived records were stored in a locked room within the Centre. Access to records is restricted to authorised personnel only.

Areas for improvement
None

Areas for consideration
A low level air extractor was seen to be in place in the cryostore in addition to four low level oxygen sensors. Two were reported as being on fault on the day of the inspection due to checking of the generators. The Person Responsible has since informed the Executive that the fault was corrected the day after the inspection.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
None

Evaluation
No improvement required

4. Information

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

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
Patient information provided for the inspection was considered by the inspection team to be satisfactory. It is compulsory for patients to attend an information evening prior to embarking on a treatment cycle. Patients interviewed on the day of the inspection were satisfied with the information they had received and gave their consent for the inspection team to observe their consultation. The inspection team was informed that regular meetings are held within the Centre. Minutes of the following were seen by inspectorate: • Office staff meetings – the file contained several sets of minutes of meetings including ones for meetings that took place in September and November 2007, January and February 2008. • SMAG minutes –for September, November and December 2007 and January 2008. They recorded that matters discussed included patient satisfaction surveys, Healthcare Commission, HFEA alerts and matters arising from previous meeting. A Welfare of the Child (WoC) protocol is in place. The Centre team has access to an ethics committee and the PIQ stated that there had been 18 referrals in the previous twelve months. It was explained to the inspection team that this relatively high number of referrals was due to the complex background of some NHS funded

patients.

The Centre conduct 'home assessments' in relation to WoC – they are done by social workers. The Centre has a procedure for communicating with patients who are refused treatment.

A written protocol on confidentiality is in place. The PIQ stated that all staff are aware of confidentiality requirements of the HFE Act (1990) and had signed confidentiality statements.

Computer systems storing confidential data within the unit are password protected and part of a wired local area network, separate from the hospital systems. Back-up database information is kept within a fireproof safe.

The Centre team is currently recruiting sperm donors. They report that this programme is progressing. The donors will be for sole use of the Centre. An SOP is in place detailing the recruitment policy, consultation, screening and acceptance criteria, donation process and release policy. Donors are asked if they have previously donated samples at any other Centre in the UK or otherwise. They are also required to produce a copy of the photograph page.of their passport.

Lot numbers of equipment used is documented on patient records in addition to a batch record file. This was evidenced by the scientific inspector in:

- Patient files
- Theatre book
- Batch record file

The scientific inspector was informed that the Centre intends to introduce electronic witnessing which will be used initially alongside manual witnessing.

The inspection team was informed that in exceptional cases (approximately once or twice a year) men produce their semen samples at home. An SOP is in place and the Centre will not accept the sample unless the man himself brings it to the Centre.

Surrogacy treatments are seldom performed at the Centre.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Donor registration Procurement and distribution of receipt of gametes and embryos Packaging and distribution Labelling of packages containing procured gametes

Transportation, labelling of shipping container and recall Receipt of gametes

Evaluation
No improvement required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	0.9
NMC registered nurses	2.32
HPC registered scientists	2.9
Scientists working towards registration	2.0
Support staff (receptionists, record managers, quality and risk managers etc)	4.24
Counsellors	1.0

Summary of laboratory audit / Audit of records
An audit of stored material was performed in January 2008. No discrepancies were found between the records and material stored. Patient files reviewed by the inspection team were found to be in good order. The files contained the necessary consents, signatures and WoC forms. The documents were all in order and all of the men had consented to posthumous registration. A file relating to a patient who had been refused treatment was also examined – the reason for refusal was clearly communicated in a letter and the patient was also informed about how to access counselling.
Summary of spot check of stored material
There were no discrepancies highlighted in a spot check of stored material performed on the day of inspection.
Areas of firm compliance
Validation: Data was seen on inspection which was to be written into a report. It is in draft form for most processes. The scientific inspector was informed that some equipment is validated by the suppliers. CE marked equipment is used where available.

The Centre submitted their witnessing audit for inspection. This was found to be satisfactory.

The witnessing protocol was submitted for inspection and met the requirements of the Code of Practice.

Laboratory SOPs submitted for the inspection were seen to document:

- Date of issue
- Date of overview
- Edition no.
- Created by
- Authorised by
- Location of copies

The PIQ stated the following:

- Staff records are audited on an annual basis. Staff are required to be a member of a relevant professional body and to produce their annual certificate which is kept with their records.

- Training needs for individuals are identified at annual appraisal. All professional staff are required to be enrolled in respective CPD programmes.

- Trainee embryologists are registered with ACE and have a nominated supervisor. Nursing staff undergo an induction programme as per SOP. Office staff have an in house training programme

- All professional staff are required to be registered with their professional bodies for CPD.

- There is an in house CPD seminar scheme.

The inspection team was informed that the consultants are registered with their relevant professional bodies, have annual appraisals and professional development plans.

The situation is similar for the nurses.

All staff undertake the Trust's mandatory training (for CPR, infection control etc) and undertake other training funded by the Centre.

Staff were encouraged to attend conferences/training and the inspection team was told that it was rare for training requests to be refused.

Evidence of competencies was seen for members of the nursing and laboratory team.

In instances of clinical emergency there is an on call system and access to National Health Service facilities including resuscitation.

Patients can have up to six sessions of counselling free. The counsellor sees patients at a

location away from the Centre. She attends the SMAG meetings and feels she is an integral part of the staff team. She has a colleague who can provide cover when she is on holiday and who could also be available in an emergency.

The counsellor attends the patient information evenings.

There is no waiting list for counselling appointments.

Areas for improvement
None

Areas for consideration
In a patient file reviewed for compliance and documentation of witnessing, a witnessing signature on one of the record sheets was missing. It was explained to the inspection team that this patient had a large number of eggs and therefore three laboratory sheets were necessary to record the fate of all the eggs. The witnessing signature for the procedure had been completed on two of the sheets but was missing on the third sheet. The embryologist acknowledged that the third signature should have been in place but was confident that the procedure had been witnessed. This explanation appeared reasonable to the scientific inspector. The staff provided evidence for all but one of their competency training requirements. The specific competence training in question had been provided, but written documentation was not recorded. Staff were reminded to obtain documented evidence of all training. Mandatory life support training to be updated. Since the inspection the Lead Nurse has informed the Executive that all the nurses apart from herself are up to date with resuscitation training. She is booked to attend shortly.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
None

Evaluation
No improvement required

Report compiled by:

Name…Janet Kirkland

Designation…Inspector

Date…4 April 2008

Appendix A: Centre Staff interviewed

Person Responsible

Nominal Licensee

Four additional Centre staff

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Valid from	Valid to
L0021/11/a	Active	Treatment with storage	05/07/2007	30/09/2008
L0021/10/a	Replaced by new version	Treatment with storage	01/10/2005	30/09/2008
L0021/9/b	Replaced by new version	Treatment with storage	17/11/2003	30/09/2005

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number…0021……

Name of PR……Mr Steve Maguinness…….

Date of Inspection…4 March 2008……..

Date of Response……7 May 2008……

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

Signed……

Name……Steve Maguinness…….

Date……7 May 2008……

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).

Attachment detailing comments on inspection report for centre 0021:

Page 18:

The WTE staff hours are not listed.

GMC registered : 3 Consultants providing 0.9WTE + on-call availability.

HMC Nurses: 2.32 WTE (+clinical support worker 0.64 WTE)

HPC Registered Scientists: 2.9 WTE
Working to Reg 2.0 WTE

Support Staff; 3.6WTE

Counsellor: 1 (plus back-up availability).

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Areas for consideration, paragraph 2.

We are concerned that this paragraph gives the impression that the nurses are missing competences.

Whereas what was missing was documentary evidence of one specific competence training which had in fact taken place.

We think this paragraph should include:

The staff provided evidence for all but one of their competency training requirements. The specific competence training in question had been provided, but written documentation was not recorded. Staff were reminded to obtain documented evidence of all training.
(this has now been changed in the body of the report following approval by a Licence Committee)

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

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