Renewal Inspection Report

Derby City General Hospital
Centre 0149

Date of Inspection: 28 May 2008
Date of Licence Committee: 1 September 2008

CENTRE DETAILS

Centre Name	Derby City General Hospital
Centre Number	0149
Licence Number	L0149/8/b
Centre Address	Fertility Unit Women's and Children's Services Derby City General Hospital Uttoxeter Road Derby DE22 3NE
Telephone Number	01332 785 643
Type of Inspection	Renewal
Person Responsible	Mr Joe Darne
Nominal Licensee	Professor Robert Shaw
Inspector(s)	Allison Cummings
	Dr Andy Leonard
	Ellie Suthers
Fee Paid – up-to-date	Yes
Licence expiry date	31/10/2008
NHS/Private/Both	NHS

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About the Inspection:
This inspection visit was carried out on Wednesday 28 May 2008 and lasted for 5.5 hours. The report covers the pre-inspection analysis, the visit and information received between 27 April 2005 and 28 May 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 fertility unit at Derby City General Hospital was first licensed by the HFEA in 1995 for donor insemination (DI). Since the implementation of the European Tissues and Cells Directive (EUTCD) in July 2007, the centre is now licensed for intrauterine insemination (IUI).

The fertility unit also provides a satellite service to CARE Nottingham (centre 0101) and patients are referred there for in vitro fertilisation (IVF). The PR stated that there is opportunity to expand the centre's involvement in this arrangement so that more patient monitoring occurs in Derby although there are no timescales for this.

In December 2007, the centre moved from their temporary premises of the previous 18 months to spacious new premises within the same hospital grounds. The centre re-commenced HFEA licensed treatment in March 2008 after the License Committee was notified. The Committee noted that the premises were suitable and agreed that they were content for licensed work to recommence.

Treatment is available all days of the week, depending on patient needs. The fertility unit is open 08:30 – 15:30 Mondays, Thursdays and Fridays; 08:00 – 17:00 Tuesdays and Wednesdays; and 08:00 – 12:30 Saturdays and Sundays.

The person responsible is a consultant obstetrician and gynaecologist and has maintained registration with the General Medical Council since 1979. He is also a Fellow of Royal College of Obstetricians and Gynaecologists.

Activities of the Centre

The centre's activity was informally discussed in the course of the inspection. Although the centre is licensed to carry out DI, no cycles have been performed since January 2007. The PR commented that donor sperm has been difficult to obtain from other licensed centres within the UK.

The PR reported that 34 patients received IUI in the 2007/08 financial year for which they are each funded for up to 6 cycles by their referring primary care trust (PCT). The PR was required to report the number and outcome of IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008. However, this data has not yet been received.

As a satellite centre, the PR reported that approximately 95 patients were referred to CARE Nottingham for IVF and/or ICSI in 2007.

Summary for Licence Committee

The executive recommends that the centre's licence is renewed for four years.

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
1. A third party agreement with the supplier of catheters used for insemination has not been formalised.	The centre should establish a written agreement with third parties for external activities which influence the quality and safety of gametes and embryos procured or processed and in particular where: (b) A third party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution (Standard License Condition A.5.1).	This will be monitored at the next inspection.
2. Portable appliance testing of the incubator, centrifuge, whirlimixer and socket boards was due in April 2008.	The centre should ensure that all critical equipment is preventatively maintained in accordance with the manufacturers' instructions as required by Standard 6.4.2 (a).	With immediate effect.
3. Procedure and equipment validation is not yet been performed.	Laboratory procedures and equipment should be validated as required by Standard 7.8.3.	To be monitored at the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
4. The centre's method of witnessing (manual or electronic) has not been risk	Complete and submit a risk assessment to the executive.	31 July 2008

assessed in accordance with CH (07)02.		
5. The centre's witnessing practices were broadly compliant with HFEA witnessing guidelines. The form capturing witnessing signatures in patient records does not however allow witness signatures, and their dates and times (as required by Guidance 13.2.1(b)), to be recorded for all processes which require witnessing, as listed in Guidance 13.1.1.	The document which captures witness signatures in the patient record should be amended, to allow witness signatures, with times and dates in each case, to be recorded, for all processing steps for which witnessing is required by Guidance.13.1.1.	With immediate effect

Recommendations

Actions recommended	Time scale
6. The PR should submit the centre's outcome data to the HFEA for the period 5 July – 31 December 2007. This was due by 31 March 2008.	31 July 2008
7. Since the dewar storage room is fitted with a false ceiling, the centre should consider assessing the risk of liquid nitrogen escaping through this feature into the neighbouring dirty utility room. It is recommended that the PR seeks advice and a health and safety assessment should be carried out on the cryostore in order to identify any potential hazards to staff and/or visitors.	

Proposed licence variations by last Licence Committee

None.

Changes/ improvements since last inspection: new premises

Recommendations	Action Taken
PR to inform the lead inspector of the staff changes within the laboratory including staff name, job title, professional registration number (if applicable) and dates of commencement/leave.	Yes. The PR supplied all staff details as requested.

In accordance with Standard 6.2.1 and 6.2.7, laboratory staff that are new to carrying out HFEA licensed activity should be provided with appropriate initial/basic training which is updated as required when procedures change or scientific knowledge develops.	Yes. The executive were provided with completed induction and training plans for all laboratory staff at the January 2008 'new premises' inspection.
In accordance with standard licence condition A.10.19, the environment in which gametes are processed and the background environment should be tested and monitored for compliance.	Yes. Testing reports were provided to the inspection team. See section 3: premises and equipment for further detail.
PR should risk assess the local alarm system for the dewars in the new cryostore, identifying if there is a need for additional controls such as the acquisition of an external audio visual alarm. The outcome should be an effective alarm system as outlined in G.9.3.1.	An external alarm has been fitted and this was shown to the team at the renewal inspection.
PR should submit a form for the 'Notification of changes to the current licensed premises (within curtilage) or change of equipment'. Note: design plans for the new premises are required to be submitted as part of this application.	Yes. The Licence Committee were notified of the new premises on 6 March 2008.

Additional licence conditions and actions taken by centre since last inspection

None.

Report of Inspection findings

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of 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 PR submitted his Person Responsible Entry Programme in a timely manner to the executive. The responses demonstrated that the PR a good understanding of his role and responsibilities. • The PR reported that information is disseminated to staff through either of the bi-monthly clinical and business meetings. Laboratory staff also meet monthly. • Meetings are held ad-hoc with staff from CARE Nottingham. Their last meeting was held on-site in January when the medical director of CARE Nottingham came to tour the new premises and to disseminate CARE updates. Minutes of these meetings were seen. • No incidents have occurred since the last renewal inspection. Staff demonstrated during interview they were aware of HFEA procedures for reporting incidents. • Risk assessments carried out since the last inspection included an air quality assessment, assessment of the new cabinet for processing samples and an assessment of moving the dewars to the new premises. • All minutes of staff meetings and risk assessments are displayed on the staff room notice board: staff are asked to confirm that they have read the documents.
Areas for improvement
• The quality manager reported that all third party agreements have been formalised except for the supplier of catheters for insemination. This is because the quality manager was unsure about who the agreement should be with, i.e. the purchasing department within the hospital or directly with the manufacturer. This was resolved on inspection and the quality manager agreed to formalise the agreement with the purchasing department which supplies the goods, as per HFEA guidance notes.
Areas for consideration
• At the initial meeting with key staff the inspection team were informed that one administrator had left in January and has not been replaced. As a result, clinical staff spend more time on administration duties and the reception telephone can be left attended at times. A small

number of patients have complained that they can't contact the centre by phone at times. These were documented on the centre's complaints register. The PR added that the situation is being monitored by staff and hospital management are aware of the issue.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Payment of treatment fees.

Evaluation
Some improvements required.

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

Summary of findings from inspection:

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
10. Counselling

Live Birth Rates
• There is no recent DI outcome data to present. • The PR was required to report their IUI activities, including live birth rates, for the period 5 July – 31 December 2007 to the HFEA by 31 March 2008. The HFEA has not yet received these data. It is recommended that this be submitted at the earliest possible opportunity.
Areas of firm compliance
• The quality manager for the fertility unit has established a quality manual and this was shown to the lead inspector. He meets with staff in the unit on a monthly basis to discuss their progress and minutes of these meetings were seen: meetings also cover other quality aspects of the service such as patient feedback. • The centre's most recent progress has included up loading protocols onto the document management system, Q Pulse, and devising an audit plan for the laboratory. A sample of protocols seen on inspection were adequately controlled. • Another database, 'documanager' from CARE, is soon to be installed. The inspection team were informed that this will be entirely dedicated to patients who are referred to Nottingham for IVF. • A register of patient complaints was reviewed. Records indicated that these had been investigated and resolved, except for one complaint which is ongoing. The quality manager stated that the gynaecology directorate meet quarterly to review formal complaints. A 'concerns and compliments' sign was visible in the waiting area, identifying the method for raising these. A request has also been made for a comments box. • Five HFEA patient questionnaires were returned between April and May prior to the inspection. The comments were generally positive towards the facilities, staff and overall treatment they received. • Key performance indicators relate to waiting list dynamics and treatment success rates. The PR reported that there is currently a nine week waiting time for IUI patients, which is within the 18 week national target. • The counselling service is provided by CARE Nottingham. Notices advertising the service were observed in the waiting area. • In the event a patient wishes to contact the centre out of hours, the fertility nurse stated that

patients can leave a message or in the event of an emergency, make contact with their GP, NHS Direct or the gynaecology department. As IVF patients have access to an out of hours service provided by CARE Nottingham, it was thought that the current arrangement for IUI patients was adequate.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Staff suggestions

Evaluation
No improvements needed.

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. Laboratory facilities
4. Air quality
5. Storage facilities for gametes and embryos
6. Staff facilities
7. Management of equipment and materials
8. Control of records
9. Risk assessments

Areas of firm compliance
• The new premises are spacious and have accounted for a future increase in activity. Before re-commencing licensed activity in March 2008, the new premises were inspected on two occasions. • Four dewars (containing five sperm samples) are located in a dedicated storage room. Each dewar was fitted with a low liquid-nitrogen alarm. They also have a spare dewar for emergency use. The door is locked under key and hazard notices were apparent on the door. An external oxygen depletion monitor was fitted in April 2008. • The inspection team were shown test results which demonstrated compliance with HFEA air quality requirements. Settle plate testing takes place on a weekly/bi-weekly basis to monitor the air quality. • Equipment servicing and maintenance logs were present. Key equipment sampled by the inspection team had been maintained within the servicing interval. A brand new class II cabinet was fitted in December 2007 and is due for its first service in June 2008. • The inspection team found that records are kept for monitoring and cleaning key pieces of equipment, such as the incubator, class II cabinet and fridge.
Areas for improvement
Portable appliance testing on the incubator, centrifuge, whirlimixer and socket boards was due in April 2008. The centre should ensure that all critical equipment is preventatively maintained in accordance with the manufacturers' instructions as required by Standard 6.4.2 (a).
Areas for consideration
• Comments from two independent sources suggested that noise from the main corridor was a problem for those attempting to produce a sample in the male production rooms. The inspection team asked the PR to consider means of reducing outside noise. • The inspection team found that although there are documented procedures in place for responding to the low level oxygen alarm, night staff and the neighbouring gynaecology department have not been made aware of the procedure to responding to the alarm. The PR may wish to consider informing other staff of the centre's procedures who may be involved in the event of an emergency. • Since the dewar storage room is fitted with a false ceiling, the centre should consider

assessing the risk of liquid nitrogen escaping through this feature into the neighbouring dirty utility room. It is recommended that the PR seeks advice and a health and safety assessment should be carried out on the cryostore in order to identify any potential hazards to staff and/or visitors.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
None.

Evaluation
No improvements needed.

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. Procurement and distribution of receipt of gametes and embryos
12. Home procurement report documentation
13. Labelling of packages containing procured gametes

Areas of firm compliance
• The fertility nurse specialist stated that the centre has a nominated person to retrieve alerts from the HFEA website. These are made available on the staff room notice board. They are asked to sign to confirm the alerts have been read. • The fertility nurse specialist reported that in cases where patients receive HFEA licensed treatment, health records are stored securely in locked filing cabinets within a dedicated locked room in the centre. • A log is kept for recording the batch number and expiry dates of stock that could potentially affect the quality and safety of gametes, such as sperm preparation medium, flushing medium, catheters and other consumables. • Labelling of sperm samples were seen to be appropriate. • There is no home procurement documentation as the centre requires that all samples are produced on site. The inspection team observed documentation which demonstrated that sperm procurement is compliant with HFEA requirements.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Donor information Donor registration

Evaluation
No improvements needed.

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. Training and continued professional development
6. Witnessing

Full time equivalent staff

GMC registered doctors	1.0
NMC registered nurses	2.46
HPC registered scientists	0.9
Scientists working towards registration	0
Support staff (receptionists / quality managers)	1.55 / 1.0
Counsellors	0

Summary of laboratory audit / Audit of records
• The most recent laboratory audit report was provided to the inspection team at the December 2007 'new premises' inspection. No discrepancies were found. It was noted that there were very few samples in storage, with the majority being stored for sibling use.
Summary of spot check of stored material
• Due to the small number of samples in storage, a spot check was not performed.
Areas of firm compliance
• The senior biomedical scientist reported that all laboratory staff participate in the UK NEQAS scheme, a form of external review. In March 2008, two staff members attended a UK NEQAS andrology study day: semen analysis practical day course. • Training and continuous professional development (CPD) was discussed with both the senior biomedical scientist and the fertility nurse: ▪ The senior biomedical scientist reported that she is currently studying for a certificate in laboratory andrology: diagnostic semen analysis through the Association of British Andrologists (ABA). She confirmed that her competency has been assessed and completion of the course will enable her to supervise/assess other junior staff next year. Additional training documents shown to the inspection team indicated that training in the previous year was provided. ▪ Training and induction records for the new laboratory staff were reviewed at the last inspection in January 2008, enabling them to carry out their designated tasks. ▪ Although the most recently recruited nurse was not available to interview, the inspection team discussed the training she received since she commenced with the centre in January of this year. Records of mandatory training and assessments of

competency were complete. The inspection team were also shown evidence of a thorough induction process and mentorship program.
    - Attendance records were observed for 'obtaining written consent' and venepuncture provided by the Trust. Two fertility nurses who perform IUI were able to provide evidence that their competency had been assessed.
- A review of witnessing documented procedures found that they are compliant with HFEA guidelines. The senior biomedical scientist stated that one sample is ever processed in the laboratory at a time.
- The laboratory was inspected by Clinical Pathology Accreditation UK as a satellite to the main pathology laboratory for the first time in March 2008. It was successfully accredited and the certificate was shown to the inspection team.

Areas for improvement

- The inspectorate found the centre had not yet considered the most suitable method of witnessing (electronic or manual) for their local situation as requested in CH (07)02. The laboratory manager commented that they will continue to witness manually and that the risk assessment will be documented.
- Process and equipment validation has not yet been performed. Staff interviewed were advised that it is now a requirement in accordance with Standard 7.8.3.
- The centre's witnessing practices were broadly compliant with HFEA witnessing guidelines. The form capturing witnessing signatures in patient records does not however allow witness signatures, and their dates and times (as required by Guidance 13.2.1(b)), to be recorded for all processes which require witnessing, as listed in Guidance 13.1.1. The document which captures witness signatures in the patient record should be amended, to allow witness signatures, with times and dates in each case, to be recorded, for all processing steps for which witnessing is required by Guidance.13.1.1.

Areas for consideration

- The inspection team were informed that the 2008-09 budget does not allow for external training courses. The centre is reminded that 'adequate opportunities shall be given for relevant professional development' (Standard 6.2.7) and therefore consideration should be given to the individual CPD needs of staff employed at the centre.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to the areas for improvement cited above.

Areas not covered on this inspection

None

Evaluation

Some improvements required.

Report compiled by:

Name Allison Cummings

Designation Inspector

Date 19 June 2008

Appendix A: Centre Staff interviewed

The person responsible and five other staff.

Appendix B: Licence history for previous 3 years

6 March 2008: Notification of Refurbished Premises and new premise address
The Committee noted that the premises were suitable and agreed that they were content for licensed work to recommence.

14 May 2007: Variation of Licence under the EUTCD legislation
The Committee agreed to vary the centre's licence to incorporate the requirements of the EUTCD.

8 June 2006: The centre put forward plans to move premises for a period of 18 months whilst its current premises are being refurbished. The Executive stated they would be visiting the centre again on 13 June to witness the centre's progress. The Committee agreed to licence the temporary premises subject to satisfactory reports of a site visit from the Executive.

11 July 2005: Consideration of renewal inspection report
The Committee agreed to renew the centre's licence for 3 years with no additional conditions.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number	0149
Name of PR	J DARNE
Date of Inspection	28/05/08
Date of Response	21/07/08

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

Signed

Name	Mr J Darné
Date	21/07/08

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).

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

Page 6 – Breach 1 (b) Third party being set up with different supplier Breach 2 and 3 Completed already Breach 5 Enclose amended witnessing page Enclosure information re Dewar Room

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

Licence Committee Meeting

1 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Derby City General Hospital (0149)
Licence Renewal

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
Sally Cheshire, Lay Member	Claudia Lally, Committee Secretary
David Archard, Lay Member	
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Observing: Angela Sutherland, HFEA Inspector
	Providing Legal Advice to the Committee: Graham Miles, Morgan Cole

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

The following papers were considered by the Committee:

- papers for Licence Committee (34 pages)
- no papers were tabled.

1. The papers for this item were presented by Allison Cummings, HFEA Inspector. Ms Cummings informed the Committee that this centre has been licensed since 1995 and offers DI and IUI. Ms Cummings reported that the renewal inspection visit took place on 28 May 2008 and found a number of areas for improvement, listed at pages 6 to 7 of the inspection report.

2. Ms Cummings listed the areas for improvement identified in the report, these were:
   - a third party agreement had not been formalised with the centre's supplier of catheters
   - portable appliances had not been tested by the due date of April 2008.
   - procedures and equipment had not yet been validated
   - the centre's methods of witnessing had not been risk assessed

- the signature form for witnessing procedures does not allow room for dates and times to be recorded
- the centre's outcome data for the period 5 July to 31 December had not been submitted to the HFEA by the due date of 31 March 2008.
- the centre had not assessed the risk of liquid nitrogen escaping through the false ceiling of the cryostore into the neighbouring utility room.

3. Ms Cummings summarised the response to the inspection's findings received from the Person Responsible and appended at page 20 of the report. This response highlighted the follow up action being taken by the centre to address the concerns of the inspection team. Ms Cummings recommended that the centre's licence be renewed for a period of four years.

The Committee's Decision

4. The Committee noted that the centre would need to review its counselling arrangements should it recommence treatment with donor gametes.

5. The Committee decided to renew the centre's licence for a period of four years.

Signed…… … Date……..
Walter Merricks (Chair)