Interim Inspection Report

The Rosie Hospital
Centre 0051

Date of Inspection: 12 May 2009
Date of Licence Committee: 30 July 2009

Centre Details

Person Responsible	Mr Raj Mathur
Nominal Licensee	Miss Amanda Cahn
Centre name	The Rosie Hospital
Centre number	0051
Centre address	Centre for Reproductive Medicine and Surgery Cambridge University Hospital trust The Rosie Hospital Robinson Way Cambridge, CB2 2SW
Type of inspection	Interim
Inspector(s)	Miss Allison Cummings
	Dr Lynne Nice
Fee paid	Not applicable
Licence expiry date	30 September 2011
NHS/ Private/ Both	NHS

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About the Inspection:

This inspection visit was carried out on 12 May 2009 and lasted for four hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of 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 Rosie Hospital has been licensed by the HFEA since 1992. The centre is currently licensed for storage of sperm only.

The centre's licence was last renewed in 2006 for a period of five years. There were no recommendations made in relation to the centre's practice.

Mr Raj Mathur has been in post as the person responsible (PR) of the centre since 2007. He registered with the General Medical Council and in 2003 joined the specialist register for obstetrics and gynaecology.

Activities of the Centre[1] for the time period from 17 December 2007

Storage of gametes	yes

Summary for Licence Committee

The unit has appropriate premises, suitably qualified and experienced staff and in general adopts appropriate clinical and laboratory procedures. The centre has been proactive in the development and implementation of a quality management system.

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

- Storage of gametes without effective consent
- The documentation of training and assessment of competency
- Document control
- Revision of witnessing procedures and practice.

The inspection team supports the continuation of the centre's licence subject to compliance with the recommendations within the prescribed timeframes.

The licence committee is asked to review the content and recommendations in this report in the context of the low level of complexity of the organisational structure and service provided by the centre.

[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.

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
Effective document control was applied to the majority of documents reviewed during the course of the inspection. However, one document (*'transferring sibling sperm to another unit'*) reviewed in the course of the inspection was different from the version supplied to the executive pre-inspection. The inspection team noted that it was labelled with the same version history but documented a different procedure. The existence of multiple versions of a document could lead to confusion with different staff members following different procedures.	The PR should ensure that documents are uniquely identified: identification shall include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification. (CoP S.5.2.6 (b))	With immediate effect.
An audit of stored material indicated that some material had been stored without effective consent: In one instance, gametes frozen on 4th and 8th February 1999 were due to be discarded in February 2009, since the gamete provider consented to storage for 10 years. However, the samples were discarded on 26 March 2009 (when the audit was carried out).	This is a breach of Schedule 3 section 8(1) of the Human Fertilisation and Embryology Act 1990 which states that: *'a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent'*. This is supported by Schedule 3 section 1 requires that:	With immediate effect

	'a consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn'. It is recommended that the centre operates a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes in storage. (CoP 7th Edition G.9.9.1)	
The pre-inspection questionnaire states that a nurse's competency is assessed as part of their annual appraisal. Nursing staff are assessed against the national fertility nurse competencies. This competency framework does not include laboratory specific tasks such as the distribution and receipt of gametes and witnessing.	The training programme for nurses should ensure and document that each individual has competence in the performance of their designated tasks (CoP S.6.2.7 9 (a)).	To be monitored at the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
The laboratory worksheet in use at the time of the inspection did not capture the following witnessing steps: • removal of gametes from cryopreservation (CoP G.13.1.1 (i)) • transporting gametes or embryos (CoP G.13.1.1 (k)).	The centre's procedures and practice should be reviewed in consideration of CoP G.13.1.1.	With immediate effect

Changes/ improvements since last inspection

No recommendations made the report of the change of premises inspection carried out on 1 November 2007. Prior to this, the centre received a renewal inspection on 2 May 2006 when the centre was licensed for donor insemination as well as storage of sperm: no recommendations were made in the renewal inspection report.

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1. Organisation

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

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

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

Areas of firm compliance
Contingency arrangements For equipment emergencies, the centre has a back up dewar for the sperm samples. In the event of PR's absence, support from colleagues would be available to continue the service. The centre also has contingency arrangements with licensed centre 0100: Bourne Hall. **Meetings / dissemination of information** In the pre-inspection questionnaire, the PR states that weekly meetings are held with the fertility team to discuss incidents, complaints, and risk management issues. **Payment of licence/treatment fees** HFEA finance department state no invoices are outstanding at this time.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
Resource management Alert management

Establishment of third party agreements

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

Areas of firm compliance

Quality management system

The centre has established a QMS in compliance with CoP S.5.1.1. The PR stated in the pre-inspection questionnaire that the QMS was assessed in August 2008 by an external consultancy firm for ISO 9001: accreditation was awarded. The quality manual outlines its management commitment to developing and improving the QMS through:

- leadership
- communicating the importance of meeting patient, regulatory and legal requirements throughout the fertility unit
- establishing a quality policy and objectives
- conducting management reviews of the QMS
- ensuring the availability of resources.

Quality policy

The quality policy was supplied prior to the centre's inspection. It is compliant with CoP S.4.2.3.

Quality manual

The centre has established a quality manual and its content is compliant with that specified in CoP S.5.2.3-4.

Quality objectives and plans

The centre has established quality objectives. These are in accordance with the service objectives.

Quality management review/evaluation

The quality manual was issued on 1 July 2008 and therefore it had not been reviewed by the centre at the time of the inspection. The centre will be re-assessed for its compliance with ISO 9001 in August 2009.

Internal audits of the QMS are carried out bi-annually. Those carried out on 1 April 2009 included:

- Documentation and data control

- Training
- Customer complaints
- Contracts
- Objectives
- Systems audit (including policy and customer satisfaction).

Areas for improvement

Document control

Effective document control was applied to the majority of documents reviewed during the course of the inspection. However, one document (*'transferring sibling sperm to another unit'*) reviewed in the course of the inspection was different from the version supplied to the executive pre-inspection. The inspection team noted that it was labelled with the same version history but documented a different procedure. The existence of multiple versions of a document could lead to confusion with different staff members following different procedures.

Areas for consideration

None

Executive recommendations for Licence Committee

The PR should ensure that documents are uniquely identified: identification shall include a unique identifier, the edition or current revision date, or revision number, the number of page/total number of pages (where applicable), authority for issue, and author identification. (CoP S.5.2.6 (b))

Evaluation

No improvements required

Areas not covered on this inspection

None

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
- Counselling facilities
- Laboratory facilities
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Storage facilities for gametes and embryos Sperm samples are kept in a tank within the stem cell laboratory. The tank is locked so as to restrict access to only those members of staff on the centre's licence. The tank containing sperm samples is connected to a nitrogen auto-fill and monitoring system. This means that levels are monitored constantly. An on-call rota is in place to respond in an emergency. Members of staff participating in the on call rota were added to the centre's licence following the centre's last inspection in November 2007. CCTV is in operation outside of the stem cell laboratory. Access into the laboratory is restricted by a card system. A list of permitted staff is kept and prior to being granted an access card staff are provided with training on handling and storage of liquid nitrogen and safety issues relevant to the cryostore. A spare dewar is available in case of an emergency. **Storage of records** Health records are kept in locked filing cabinets within the administration office of the fertility unit.
Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
Counselling facilities Staff facilities

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
Information was not reviewed during the course of this inspection.
Areas for improvement
Areas for consideration
Executive recommendations for Licence Committee
Evaluation
Areas not covered on this inspection
Information for service users Consent Welfare of the child Access to health records Provision of information to the HFEA register

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
- 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	0.5
NMC registered nurses	4.4
Non NMC registered clinical staff	0
HPC registered scientists	0
Scientists working towards registration	5
Support staff (receptionists, record managers, quality and risk managers etc)	3
Counsellors	Session basis

Summary of laboratory audit
The centre's last audit of stored gametes was carried out on 26 March 2009. In the pre-inspection questionnaire, the PR stated that no non-conformities were identified. However, when the audit was reviewed by the inspection team, it was noted that in one instance gametes had been stored without effective consent. The gametes were frozen on 4th and 8th February 1999 and were due to be discarded in February 2009, since the gamete provider consented to storage for 10 years. However, the samples were discarded on 26 March 2009 (when the audit was carried out). As there were other samples coming to the end of their consented storage period and the centre does not have a bring forward system to alert staff of these, the inspection team were concerned that the centre may continue to breach Schedule 3 8(2) of the Human Fertilisation and Embryology Act 1990.
Summary of spot check of stored material
A spot check of stored material was not carried out on this inspection.
Areas of firm compliance
Areas for improvement
Staff training and competency The pre-inspection questionnaire states that a nurse's competency is assessed as part of their annual appraisal. Nursing staff are assessed against the national fertility nurse

competencies. This competency framework does not include laboratory specific tasks such as the distribution and receipt of gametes and witnessing.

Laboratory practice: witnessing
The centre recently changed their laboratory worksheets. The version in use at the time of the inspection did not capture the following witnessing steps:

- removal of gametes from cryopreservation (CoP G.13.1.1 (i))
- transporting gametes or embryos (CoP G.13.1.1 (k)).

Areas for consideration

None

Executive recommendations for Licence Committee

The centre is in breach of Schedule 3 section 8(1) of the Human Fertilisation and Embryology Act 1990 which states that:

'a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent'.

This is supported by Schedule 3 section 1 requires that:

'a consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn'.

It is recommended that the centre operates a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes in storage. (CoP 7th Edition G.9.9.1)

The training programme for nurses should ensure and document that each individual has competence in the performance of their designated tasks (CoP S.6.2.7 9 (a)).

The centre's procedures and practice should be reviewed in consideration of CoP G.13.1.1.

Evaluation

Some improvements required

Areas not covered on this inspection

Counselling practice

Report compiled by:

Name	Allison Cummings
Designation	Inspector
Date	16 June 2009

Appendix A: Centre staff interviewed

The PR and one other staff member.

Appendix B: Licence history for previous 3 years

Licence committee 17 December 2007
The Committee noted the centre's application to vary the licence and agreed to grant the application to change the Nominal Licensee and to change the centre's treatment and storage licence to a storage only licence.

Licence Committee 20 June 2007
On strength of the documentation received, the Committee approved Mr Singh as a suitable person to take over the role of Person Responsible.

Licence Committee 14 May 2007
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.

Licence Committee 10 July 2006
The Committee noted the centre's low risk score and agreed to renew the centre's licence for a period of five years with no additional conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0051……

Name of PR……Raj Mathur…….

Date of Inspection……12th May 2009……..

Date of Response……9th July 2009……

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

Signed……

Name……R S Mathur…….

Date……9th July 2009……

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.

We have a storage license only and sibling donor sperm samples are stored in an HTA-licensed stem cell facility.

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

1. We have altered out protocol and now operate a 'bring-forward' system for disposal of stored sperm samples at the end of the statutory period (or such shorter period as specified by a person who provided the gametes) 2. Witnessing of gamete removal from cryopreservation and gamete transport is now included in the laboratory worksheet 3. We have reviewed our version control procedures for documents. The Quality Manager has reviewed the document control policy to ensure that all documents are uniquely identified: identification includes the name of the document, current version, version/revision date, number of the page/total number of pages, authority for issue and author identification. We cannot explain how the apparent discrepancy mentioned in the report came about. We have enforced password protection for any changes to

documents.

4. We are developing nurse competency assessment for distribution and receipt of gametes and witnessing, and this will be applied to all relevant nurses in the next 6 months.

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

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

HFEA Licence Committee Meeting

30 July 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 4

The Rosie Hospital (0051) – Interim inspection report

Members of the Committee:	Committee Secretary:
	Alexandra Tydeman
Clare Lewis-Jones (lay) - Chair	
Ruth Fasht (lay)	Legal Adviser:
Sue Price (clinician)	Graham Miles, Morgan Cole
Apologies:	
Chris Barratt (andrologist)	
Roger Neuberg (clinician)	

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 (24 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

24. The Committee noted that the Centre has been licensed by the HFEA since 1992 for storage of sperm only.

25. The Committee considered the papers, which included the report of the interim inspection including the response of the Person Responsible (PR) and previous Committee minutes.

26. The Committee noted that the inspection took place on 12 May 2009 and found the following areas for improvement:
    - Storage of gametes without effective consent
    - The documentation of training and assessment of competency
    - Document control
    - Revision of witnessing procedures and practice

27. The Committee noted that the response of the PR had addressed all of the issues and that all the recommendations had been complied with appropriately and in a timely manner.

The Committee's Decision

28. The Committee endorsed the recommendations in the report made by the executive and decided to continue the licence at this time without any additional conditions.

Signed..... Date.....19/5/09
Clare Lewis-Jones (Chair)