Human Fertilisation & Embryology Authority

Report of a Renewal Inspection at

Royal Surrey County Hospital (0159)

Date of Inspection 16th November 2005

Date of Licence Committee 27th February 2006

Contents

Key facts about the centre

Centre name	Royal Surrey County Hospital
Centre address	Department of Cytopathology Royal Surrey County Hospital Egerton Road Guildford Surrey United Kingdom GU2 7XX
Centre number	0159
Person responsible	Mrs. Barbara Seyer
Nominal licensee	Dr. Stephen Whitkar

Activities of centre

Research		None
Storage		Yes

Focus of Inspection	General
Additional licence Conditions	None
Licence expires	31 March 2006

Summary

1. The centre is a part of the Royal Surrey County Hospital operating within the NHS Trust. The centre has been active since 1994.

2. The centre provides a storage service for sperms of patients for whom fertility is likely to be compromised by forthcoming chemotherapy or radiotherapy treatment or before urological surgical procedures. In the year 2004-2005, sperm storage for forty patients was carried out.

3. The centre has had a stable staffing structure during the time covered by this report. Staff reported good opportunities for induction, CPD and training.
This is an established centre and well organised.

4. A small number of issues were identified during the inspection visit and these are summarised as below:

- It is important that the centre has low level-nitrogen alarms for all the storage dewars, and also an autodial facility for every dewar. Until the alarms are fitted an on call rota should be implemented and a copy be made available to HFEA. The oxygen alarm outside the laboratory needs to be repaired and when repairs are completed, the completion report should be submitted to the HFEA.

- The consent forms must be completed carefully and routinely with the help of the nurse so that no signatures are missing and incomplete forms are not filed.

- Patient information leaflets do not fully comply with all the requirements of the Code of Practice. A small number of omissions were discussed and the centre should submit the revised information leaflet to the HFEA.

- The Nominal Licensee, (NL) Consultant Oncologist, was interviewed and suggestion made to him that he visits the laboratory at regular intervals for holding / attending departmental meetings.

- The laboratory is proactive in carrying out quality assurance and risk assessments and in auditing outcomes. On the day of inspection, the centre team appeared well integrated and responded positively to discussions with inspectors. The inspection team supports the renewal of the centre's licence for further three years.

5. This licence renewal inspection was carried out on 16th of November.

Background to inspection

6. The on-site inspection took place on 16th November 2005.
The report was sent to the centre for review in Dec. 2005

The Centre's Context

7. The main activity of the centre is to store sperm for patients undergoing medical treatment before chemotherapy or radiotherapy, urology procedures and vasectomies, which may result in a loss of fertility in future. The patients are referred from St. Luke's Cancer Centre at the Royal Surrey County Hospital.

8. The storage of sperm is only a part of the work carried out by the department of Oncology and Cytopathology.

9. There is a concern from the Person Responsible (PR) that several patients move out of the area and do not update the centre with their current postal addresses. Thus it is difficult for them to update the records with the current contact details. This results in losing contact with such patients and eventually causes problems with discarding the samples at the end of the statutory ten year period. The centre has tried several ways including contacting the GPs but have not been fully successful in obtaining the required information.

Type of work carried out

Licensed Activity

10. The centre carries out the following licensed activity:

Storage of Sperm (only of patients as described above)

Staff

11. Staffing Profile

Person Responsible	Mrs. Barbara Sayer
Nominal Licensee	Dr. Stephen Whitaker
Andrologist	4
Nursing Staff	3
Counsellor	1
Independent Counsellor	1
Complaints Manager	Mrs. Sue Lewis

There have been no changes to the key staff in the last year.

Professional registration and continuing professional Development (CPD)

12. All the biomedical scientists and nurses are registered with the Health Professional Councils and have provided evidence of their progression in working towards registration. The completion dates were seen. The PR overall is responsible for seminology facilities in the centre. The PR has 5 CPD diplomas and progressing towards the sixth next year.

13. The Staff in the centre have access to continuing professional general and specialist education.

14. There are regular staff meetings which involve representatives of all the sections within the centre. The key decisions from these meetings are documented and disseminated to all staff. Staff reported that they are supported in meeting their training needs.

15. Overall clinical responsibilities for any queries are discussed with NL, who is a Consultant Oncologist, is registered with the GMC. They have frequent informal meetings but no formal meetings.

The Premises, equipment and other facilities

Premises

16. There has been no change in the premises since the last inspection. The centre is suitable for the activities carried out at the centre.

17. The premises are located within the Department of Oncology and Cytopathology. The centre has a laboratory, where all the dewars are kept and semen analysis and cryopreservation of sperm takes place.

Equipment

18. No change in the equipment was found.
The laminar flow cabinet is in the semenology lab. It was found that fan is kept off during the procedures. The inspection team has advised Staff to use the class II cabinet for semen analysis, (which they did have in other lab) and to do semen analysis in that lab.

Security / Confidentiality

19. The entrance to the centre is restricted by key pad lock. Unauthorised staff has no access to the Laboratory. All the records are kept in locked filing cabinets in the PR's office. The office is locked when unoccupied.

Arrangements for collecting sperm samples

20. When the Consultant Oncologist decides a patient should have storage of sperm, the first step is to have a blood test taken to determine patient's antiviral antibody status. He contacts the nurse in the Centre on telephone, and at the same time a collection pot labelled with patient's details is given to the patient. The nurse contacts the patient at home to arrange an appointment for collection of samples.

21. Most of the patients prefer to produce their samples at home and then drive to the centre. However a room is available. The centre's sperm production room is well maintained, is comfortable and suitable for this purpose.

22. When patient arrives with his sperm sample, one of the scientists personally takes the sample from the patient. Patients signatures, time and date is noted on all the notes examined that related to the handover of the samples.

Cryostore facilities, oxygen and dewar alarms

23. All the dewars are padlocked and stored in the laboratory. The laboratory door is always kept locked and access limited to the licensed personnel only. The cryostore facilities are adequate for the type and volume of activities currently carried out.

24. The centre has five dewars, two of these are fitted with low nitrogen level alarms. Three of the dewars do not have alarms but the liquid nitrogen levels are checked regularly before weekends. No autodial facilities are installed and there is no on-call rota at present. The PR reported that funding is a problem but agreed to consider ways to implement the required alarm system.

25. The patients' samples have been split between dewars.
There is an interim tank in which the samples are temporarily held until blood test results are found satisfactory.

26. The laboratory has a low oxygen level alarm. A display outside the door to the laboratory gives the current percentage of oxygen in the air inside the laboratory and a record sheet for daily monitoring was seen. This was found not to be in proper working order for the past week. The PR reported that an engineer has been contacted to carry out the necessary repairs.

Emergency facilities

27. Staff were concerned that if a dewar fails, there is no spare. Help can be provided by staff at the Woking Nuffield Hospital (centre 0144) in an emergency.

28. Emergency facilities are not required for the patients in relation to their treatment at the centre. However the centre is located within the hospital which has a 24 hour accident and emergency services.

Clinical, Nursing and laboratory Procedures

Clinical

29. The centre does not carry out any clinical procedures. The group for whom storage facilities are made available are oncology patients, urology patients and patients due to have vasectomies for medical reasons. The consultants, who see the patient for these treatments, advise them of the associated risk of infertility and give them a choice to store sperm. If these patients wish to store sperm they are referred to the centre.

Nursing

30. New protocols were submitted prior to the inspection. Protocols cover the key aspects of the centre's activities and staff reported they are informative and reflect current practice. Some protocols did not have a new version number. The PR agreed to implement a version control, and will send new versions to HFEA.

Laboratory

31. The laboratory protocols are appropriate and reflect current practice. Staff confirmed that they are easy to follow. A safe working environment is provided for the staff in the laboratory.

32. There was enough space for the reception of the specimens and handling the specimens.

33. All laboratory equipment is regularly maintained and the maintenance records were supplied at the time of inspection. There were no back-up systems for all critical equipment and the PR was asked to arrange for a spare tank to be provided.

34. There are written standard operating procedures for the cleaning of vessels, filling vessels and securing vessels. SOPs for freezing and thawing of samples were seen. SOPs for the location and duration of storage, managing contaminated samples, were all seen.

35. The centre has adopted the witnessing procedures set out in Annex H Chairman's letter CH(02)01. Procedures are in place to double check patient identification. Witnessing procedures were found to be documented in the patient's records.

36. When the cryopreserved specimen of sperm reaches the end of its storage period, patients are sent a standard letter explaining that sperm sample cannot be stored beyond the date of expiry of consent. This was discussed at length as the PR reported that she has some difficulty in contacting some patients, due to them having moved out of the area. In some cases GPs cannot be contacted since they too have moved their practices. The PR is revising the procedure for contacting patients.

Procedures for assessing clients and for assessing and screening donors

Welfare of child

37. The centre does not assess the welfare of child as it does not carry out treatment. The patients would not know if they would need to use their samples and would not be considering fertility treatment at the time of storage.

38. If the patient wishes to use their stored sperm in licensed treatment they will be referred to another centre and their samples will be transferred. Welfare of the child issues will be considered by the treating centre.

Ethical Committee

39. The centre does not have a need for an ethics committee as only storage is offered. However an ethics committee may be useful for staff when freezing sperm on agenda change patients.

Assessing and screening donors

40. The centre only stores patients own sperm samples.

Counselling process and facilities

41. The centre offers counselling to every patient and there is separate counselling for oncology treatment. Once the oncologist decides for the patients to have storage of the samples, he contacts the nurse, who is also the centre's counsellor. She contacts the patient to fix up an appointment over the telephone. When patients come in, she hands over the leaflet providing information for the further procedures.

42. The counsellor covers all aspects from producing the sample, to future use of the sperm in fertility treatment and the implications of this. Oncology patients are made aware that the loss of fertility following their treatment is not definite, but the storage is insurance in case that happens.

43. The patients usually have a few days following the counselling session before they must return with a sperm sample, unless their oncology treatment is urgent, and such conditions are rare.

44. The counsellor/ nurse is aware of all the protocols of cryopreservation. She has sixteen years of experience in oncology and has worked for 18 months in this storage centre. No additional charges are made for counselling services.

Patient Experience

Patient information

45. The information pack has not been updated since previous inspections.
The information pack is sent to all the patients prior to their visit for semen collection and at the same time additional verbal explanation and information is offered if patients have any queries.
Patients are offered opportunities to talk to the staff any time during the opening hours.

46. Patient information and leaflets are clear and appropriate; however, a number of minor omissions were discussed with PR. The centre is in the process of having a quality manager to organise all the protocols to ensure they are updated and version controlled.

47. Patients seeking treatment are informed of the limit on storage time as defined by law (ten years or until patient reaches the age of 55 years). Patients have been informed to notify the centre on an annual basis as to whether they wish to continue having storage of their sperm.

Record keeping procedures

48. A review of ten patient records was carried out on the day of the inspection. The paper work in seven sets of records was found to be satisfactory, with posthumous consent correct in all the records.

49. In two of (00)6 consent forms, there was found to be crossing out without any signatures and in one of the forms there were no signatures under one section. The PR considered that the forms were confusing to complete and has arranged for the nurse to assist patients to fill in the forms during their visit. She further agreed to take extra care to ensure the forms were completed accurately in future.

Audit

50. The centre conducted a full audit over one month, September – October 2005, and a report of the audit was submitted during the visit. All records were correct and matched with the stored semen samples.

51. The centre maintains up to date records of people who have sperm in storage so that a contact can be made with the patient before the storage period expires.

52. There are documented arrangements for the transfer of stored sperm samples between clinical facilities and the laboratory and transfer of materials between centres. The centre ensured that stored material is transported to the centre in accordance with HFEA Directions.

Spot check of tracking process for stored material

53. The inspection team traced two samples from the dewar to the laboratory record book and also to the patients notes and two samples from the patients notes, to the laboratory record book to the dewars. All samples and records were tracked without any problems.

Clinical Governance

54. The centre is part of the Royal Surrey County Hospital and adopts the clinical governance policies of the Hospital. The communication with the chief executive is via the Nominal Licensee. There is a documented procedure for reporting and dealing with any adverse incidents. The centre has no issues to date.

Risk Management

54. Members of the team have received training in risk assessment. The employee training record was supplied during this visit for the year 2004 – 2005.

55. The laboratory carries out internal quality assurance assessments and participated in the National External Quality Assessment Service (NEQAS) scheme for andorology. Health and safety including COSHH training, Infection control, Personal protection, Equipment safety, Accident/ Incident reporting and VDU use.

56. The centre has a written incident policy and all incidents are discussed at operational risk management team meetings and action plan are fed back to the relevant departments.

57. The PR finds HFEA Alerts very useful and has amended some of the protocols as a result.

Complaints

58. The centre has an appropriate complaints policy. The complaint manager gives the details of the complaints to the clinical Governance team. The centre has not received any complaints in the last few years.

Breaches of the Code of Practice or Act

59. On inspection of patient records it was found that the signatures were missing in two consent forms (00)6. Crossing out in the section was noted and in one form no signatures were found.

- Some omissions to be rectified in the patient information leaflets.
- Oxygen Alarm outside the laboratory were found to be not giving a correct reading.

Compliance with previous conditions and recommendations

Conditions

60. The centre has no additional conditions on its license.

Recommendations

61. The licence committee made following recommendations.

Recommendations	Adopted by Centre (Y/N)	Comment
The PR should install low nitrogen level alarms on all sperm storage dewars, and auto dial facilities for all the tanks and requested feed back	Partially	When alarms are fitted, the PR should set up an on call rota
Oxygen alarm to be corrected	Y	
Patients leaflets to be changed	Y	
Some protocols need to have new version control	Y	
NL to visit Laboratory sometimes	Y	

Key points for the Licence Committee

62. The inspection team supports the continuation of the centre's licence for storage of sperm.

Issues

63. The inspection team would like to draw the following points to the attention for the licence committee.

64. The main pressure on the centre is to have low level-nitrogen alarms for all the storage dewars, and an autodial facility for all the dewars. When the alarms are fitted to an autodialer, an on call rota should be arranged and implemented, a copy of rota to be submitted with HFEA. The oxygen alarm outside the laboratory needs to be repaired and PR must submit a report of the repairs.

65. The consent forms to be filled up more carefully and routinely with the help of nurse so that no signatures are missing.

66. Patient information leaflets do not fully comply with all the requirements of the COP. A small number of omissions were discussed and the centre should submit revised information leaflet to the HFEA.

Appendix A the Inspection team staff interviewed

The Inspection team

Dr.Neelam Sood	Inspection Chair, HFEA executive
Mr.David Gibbon	Scientific Advisor
Dr.Marion Witton	Head of Inspection, Observer

Centre Staff interviewed

Dr.Stephen Whitkar	Nominal Licensee
Mrs.Barbara Sayer	Person responsible
Mrs.Valerie Pink	Nurse & Counsellor
Mrs.Jan Schwick	Scientist

Conflicts of Interests

None declared