Human Fertilisation and Embryology Authority

Report of a renewal inspection at

Barts and the London Centre for Reproductive Medicine (0094)

Date of inspection 20th April 2006

Date of Licence Committee 08th June 2006

Licence expires 31st October 2006

Contents

Key facts about the centre 3
Summary 4
Background to inspection 5
The centre's context 5
Type of work carried out 6
Staff 7
The premises, equipment and other facilities 10
Clinical, nursing and laboratory procedures 11
Procedures for assessing clients and for assessing and screening donors 13
Counselling process and facilities 14
Patient experience 15
Record keeping procedures 16
Three embryo transfer arrangements 16
Audit 16
HFEA register 17
Clinical governance 17
Breaches of the Code of Practice or Act 18
Compliance with previous conditions and recommendations 18
Key points for the Licence Committee 18
Appendix A The inspection team and staff interviewed 19

Key facts about the centre

Centre name Barts and the London Fertility Centre

Centre address The Centre for Reproductive Medicine
St Bartholomew's Hospital,
2nd Floor, Kenton and Lucas Wing
Little Britain
London
EC1A 7BE

Centre number 0094

Person responsible Amanda Tozer

Nominal licensee Melanie McColgan

Activities of centre

		01/01/05-31/12/05
Licensed treatment cycles	IVF ICSI FET Egg sharing Egg donation Egg recipient	510 313 280 2 13 8
Donor Insemination		80
Research	None	
Storage	Yes	

Focus of inspection Informing patients re. the Deceased Fathers Act
Communication between the centre and its patients

Additional licence conditions None

Licence expires 31st October 2006

Summary

1. The centre is part of the Bart's and London NHS Trust. It was first licensed in 1992 and moved to the current premises in 2004. It has a good history of regulatory compliance. Self funded and NHS commissioned treatments are offered.

2. 823 IVF and ICSI treatment cycles were reported as having been performed at the centre between 01/01/05 and 31/12/05 compared to 795 in 2004.

3. The previous Licence Committee on 30th November 2005 requested that the team for this inspection focus on the arrangements for contacting patients regarding the Deceased Fathers Act and also on communication issues between the centre and its patients.

4. Following last year's inspection an administrator was appointed to oversee the arrangements for contacting patients regarding the Deceased Fathers Act. The Person Responsible has, since the current inspection informed the executive that this process has been completed.

5. With reference to communication issues between the centre and its patient's comprehensive protocols for administration and communication procedures were reviewed by the inspection team and found to be satisfactory.

6. The number of complaints received by the centre in the last 12 month period has reduced by 50% for the same period last year.

7. The inspection team support the renewal of the centre's licence.

Background to inspection

8. This renewal inspection report covers the period August 2005 to April 2006 and includes outcome data from January 2005 to December 2005.

9. A new person responsible was appointed in December 2005.

10. Patient questionnaires were distributed during January – March 2006. Completed questionnaires which had been received at the HFEA were discussed at the inspection.

11. One site visit took place on 20th April 2006 and lasted 6 hours.

12. The HFEA operational audit team visited the centre from November 29th - December 1st 2005. Key points from the audit are included in this report.

13. At the time of the inspection there were no issues with the HFEA finance department.

14. The report was sent to the Person Responsible for review in May 2006.

The centre's context

15. The centre is part of the Bart's and London NHS Trust and offers treatment to GP referred patients from Tower Hamlets, City of London and its satellite centre in Norwich. The centre has contracts with six Primary Care Trusts (PCTs): South Essex, East Sussex, Barking and Havering, Waltham Forest, King George V and Newham. Patients who are self funding also receive treatment at the centre.

16. Opening hours are Monday to Friday 0800hrs -1800hrs and 0800hrs-1200hrs on Saturdays. A staff rota to cover weekend working was seen by the inspection team.

17. The Person Responsible informed the inspection team that the number of cycles performed has increased by 43% in the previous 6 months. Staff reported that they were able to cope with the increase in workload and a further two nurses have been recruited to the team. Consideration is being made to making alterations to the patient recovery area to allow accommodation of more patients.

Type of work carried out

Licensed treatment

18. The following licensed treatments are performed:

- Donor Insemination (DI)
- In Vitro Fertilisation (IVF)
- IVF with donor eggs
- IVF with donor sperm
- Intra Cytoplasmic Sperm Injection (ICSI)
- ICSI with donor sperm
- ICSI with donor eggs
- IVF with egg sharing
- Storage of sperm
- Storage of embryos
- Assisted hatching (mechanical)

Treatments that do not need a licence

19. The following treatments are performed :

- intra-uterine insemination (IUI)
- tubal surgery
- microsurgical epididymal sperm aspiration (MESA)
- percutaneous epididymal sperm aspiration (PESA)
- testicular sperm extraction (TESE)
- host surrogacy
- ovulation induction

Satellite/transport arrangements

20. The centre has a satellite arrangement with the Norfolk Clinic in Norwich.

21. The Person Responsible informed the inspection team that the satellite arrangement in Norwich has been in place for ten years.

22. The contract for the satellite agreement was seen by the inspection team.

23. The programme is managed by the nurse manager at Barts who attends the satellite centre weekly. One of the consultants from Barts attends the centre once a month. Other staff at the satellite centre include three nurses and two ultrasonographers.

24. Patients attending through the contract arrangement are seen for initial consultation and investigations at Barts. Follow up appointments are offered in Norwich.

25. The Person Responsible informed the inspection team that she attends meeting with the PCTs two to three time a year. These meetings are also attended by the nurse manager, a consultant from the centre and a member of the finance team.

26. A contingency measure involving a transport arrangement with the Bridge (centre 0070) is in place in the event of the team at Barts being unable to perform treatments.

Staff

27. The Person Responsible has been appointed since the previous inspection. She reported that there has been an increase in workload of 43% in the previous six months. Staff interviewed were positive about their working conditions and their ability to cope with the increase in treatment cycles. Opportunities for continuing professional development were reported by staff as being satisfactory.

Staffing profile

.

Person responsible	Amanda Tozer
Nominal licensee	Melanie McColgan
Accredited consultant	Colin Davis
Other medical staff	8(2consultants,1associate specialist, 3 research fellows, 2 sub-specialist trainees)
Embryologists	7 (1 laboratory manager, 2 deputy managers, 4 qualified)
ICSI practitioner	5
Nursing staff	12(2 senior, 2 newly recruited and one health care support worker)
Independent counsellor	3
Complaints manager	Liz Latarche

28. The nurse manager reported that two nurses have been recruited to join the team in May.

Professional registration and continuing professional development (CPD)

29. The Person Responsible informed the inspection team that all staff are registered with the appropriate statutory body. New team members are recruited following the Trust's recruitment process which involves checking with the criminal records bureau (CRB).

30. There is a training budget for junior Doctors of £800 each per annum. In addition they are granted 30 study days per year.

31. The Person Responsible reported that she is up to date with her CPD points for the Royal College of Gynaecologists. In the previous twelve months she has attended The British Fertility Society (BFS) winter conference and European Society of Human Reproduction (ESHRE). She has annual appraisals and helps with the organisation of the MSC courses for Queen Mary's and contributes to the Fertility Nurse training at Barts.

32. The nurse manager confirmed that there is a training budget from the Trust for continuing education in addition to a special trustees account for funding.

33. The Nurse Manager confirmed that she is registered with the Nursing and Midwifery Council (NMC) and is a member of the Royal College of Nursing fertility nurses group attending their meetings four times a year. She is also a member of the British Fertility Society (BFS) and the Senior Infertility Nurse Group (SING).

34. Training events that she has attended in the previous twelve months include the HFEA annual general meeting and the British Fertility Society winter meeting. In addition she is chairing a session at both the National Fertility Day and the "Insights" conference.

35. A recently appointed nurse was interviewed by the lead inspector. She reported that she was satisfied with her induction to the centre team and opportunities for CPD. She provided evidence of :

- qualifications
- membership of professional bodies
- certificates of courses attended

36. An example of the induction programme and competencies check was seen by the inspection team.

37. There are eight embryologists. Six are registered with the Health Professionals Council (HPC) and the Association of Clinical Embryologist (ACE). Of the two who are not registered one is currently undertaking the ACE diploma to become HPC registered and the other is working on a voluntary basis to gain experience.

38. Pin numbers for the laboratory team were seen at the inspection.

39. The scientific inspector was informed that there is a specific budget for CPD. Examples of courses attended include the ACE meeting in Dublin, a course on how to break bad news ,a conference on oocyte cryopreservation, presentation skills and appraisal training.

40. The scientific inspector saw evidence of attendance at the ACE conference for one team member and ACE training log of another.

41. The counsellor also felt supported in her requests for CPD and attends two to three study days per year. She will be attending the national infertility day in June.

42. The centre has a comprehensive system for auditing practices and outcomes. One afternoon each month no clinics are held across the Trusts to allow all disciplines to attend audit meetings. Copies of presentations that had been given at these meetings and the forward plan for 2006 were seen by the inspection team.

43. There are several meetings held at the centre. These include:

- monthly departmental meetings
- senior management meetings
- fertility risk assessment meetings
- daily clinical meetings to discuss treatment cycles and patient care.

44. In addition minutes of meetings seen by the inspection team include:

- Audit meetings
- Laboratory staff meeting
- Fertility unit meeting
- Business and strategy meeting
- Fertility nurse meeting

The premises, equipment and other facilities

Premises

45. The centre is located on two floors of the Kenton & Lucas wing of St Barts Hospital. The ground floor contains a waiting area, two counselling rooms, archive records room and several offices. On the second floor is the reception, patient waiting area, consulting rooms, staff room, offices, record store, two theatres, recovery room, embryology, research and andrology laboratories, two sperm production rooms, patient quiet room and cryostore.

46. The inspection team considered that the premises were fit for the purpose.

Equipment

47. Since the previous inspection the centre have purchased validating data loggers for incubators, fridges and freezers. These data loggers can monitor temperature, humidity and be analysed for trends.

Security

48. Access to both floors is via a video phone system and swipe card access.

49. The previous inspection team noted three areas where security was felt to be inadequate. This has been addressed and the areas seen to be secured.

Confidentiality

50. Patients' records are filed in a room which is situated behind the reception area. This room is accessed by a number code system and is locked when the centre is closed. It was noted by the inspection team that maintenance staff may need to access this room. The team were assured that if this were the case they would be accompanied by a member of the centre team whilst they were in the room.

51. The previous inspection team had concerns regarding security of the room where archived records were stored. The records were seen by this team to be stored in a room which is locked when not occupied.

Arrangements for collecting sperm samples

52. There are two production rooms at the centre. Neither have a patient alarm. This was discussed with the centre team.

53. After producing the sample the patient delivers it to the laboratory. Should a member of the laboratory team not be present at the time the patient is required to wait in order to sign a form in the presence of the laboratory team. After following the pathway taken by the patient the scientific inspector considered this to be satisfactory.

54. Patients are encouraged to produce their samples at the centre and only on very few occasions are samples brought from home. A system should be put in place for patients to verify the identity of their sample in writing.

Cryostore facilities, oxygen and dewar alarms

55. Gametes and embryos were seen to be stored in a designated security area with controlled access.

56. The cryostore facilities are adequate for the type and volume of activities to be carried out.

57. Appropriate emergency procedures to respond to damage to storage vessels and failures in storage systems were seen by the scientific inspector.

58. Dewars are locked and alarmed.

59. A low level oxygen alarm was seen to be in place

Emergency facilities

60. The centre is situated within Bart's and the London NHS Trust and has access to the trust's emergency procedures.

61. In the event of a patient emergency, the emergency team from the main hospital can be summoned by activating an alarm beside the patient's bed in the recovery room. This procedure has been tested and found to be satisfactory.

Clinical, nursing and laboratory procedures

62. Documents reviewed by the inspection team were considered to be satisfactory. However they were not all version controlled. The inspection team were informed that this will be addressed with the introduction of a quality management system.

Clinical

63. The clinical protocols were reviewed by the clinical inspector and found to be satisfactory. It was discussed during the feedback session that it would be of benefit to have separate protocols for treatments offered rather than a document which covers many protocols.

64. Adequate protocols are in place for ovarian hyperstimulation syndrome (OHSS).

65. Barts have an agreement with several hospitals to receive patients who are resident within their catchment area should they require hospital admission.

66. In the event of a patient presenting with suspected ovarian hyperstimulation syndrome and requiring admission or transfers to a hospital other than Barts the centre team maintain daily contact with the hospital and fax protocols to them as required. The care of a patient who is admitted to Barts is overseen by the centre team.

67. Patients are informed of the risks of ovarian hyperstimulation syndrome at various stages throughout their treatment cycle. Written information given to the patients include a description of the condition and symptoms which, if they experience they should contact the centre.

Nursing

68. There are no specific nursing protocols. This was discussed with the nurse manager and the team will use the opportunity gained by recruiting new members of the nursing team to identify and create protocols where required.

69. The centre has a team of theatre staff. However the nurse manager informed the inspection team that all nurses were trained to be competent to work in the theatre area should this be required.

70. Oocyte collections are performed using intravenous sedation. The inspection team were informed that on occasions this is administered by a member of the nursing team under the guidance of one of the clinicians.

Laboratory

71. The laboratory protocols were considered to be satisfactory by the scientific inspector.

72. Written standard operating procedures for cleaning vessels; filling vessels; securing vessels; freezing and thawing procedures; location and duration of storage; handling of contaminated samples were seen by the inspection team.

73. Witnessing arrangements are in place and were seen to be documented in patient records.

74. Samples are stored for oncology patients.

75. In some instances viral positive patients may be offered treatment at the centre. Viral positive samples are always last to be processed in hoods and are kept in a separate incubator.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

76. The centre's process for conducting a Welfare of the Child assessment takes into account
    a. the commitment to raise children
    b. ability to provide a stable and supportive environment for a child/children
    c. immediate and family histories
    d. age, health and ability to provide for the needs of a child/children
    e. the risk of harm to children including inherited disorders (or transmissible diseases), multiple births, neglect or abuse, the effect of a new baby or babies upon any existing child of the family

77. The Person Responsible explained that patients have extensive medical and social history recorded and cases which have raised concern have been identified in this way.

78. In the event of the team deciding that more information is required the Person Responsible reported that relevant professionals or services would be approached.

79. Concerns relating to Welfare of the Child issues are raised at team meetings. Evidence of this was seen in the minutes.

80. The Person Responsible informs the patients of the outcome of the decision of whether to offer treatment or not. Patients who are refused treatment are offered the right to appeal.

Ethics committee

81. The staff have access to a clinical ethics committee. Cases are discussed at multi-disciplinary meetings and are therefore seldom referred to the committee.

Assessing and screening donors

82. Donor sperm is purchased from licensed sperm banks.

83. Donors are screened in accordance with national guidelines

84. Eggs donors are required to see the counsellor for a minimum of two sessions before embarking on treatment. In a “known donor situation” the donor and recipient are seen separately by different counsellors.

85. An information leaflet for patients considering donation was reviewed by the inspection team. It was considered to be both informative and comprehensive detailing several aspects of the treatment including screening tests required and the offer of support should any tests results be found to be positive.

86. The centre establishes that the limit of ten live birth events per sperm donor is not exceeded by liasing with the supplying centre.

87. Sperm has been imported by the centre team following the appropriate procedures.

Counselling process and facilities

Counselling protocols

88. Counselling protocols were reviewed by the inspection team and found to be satisfactory.

Counselling referral arrangements

89. There are two counsellors based at the centre and one at the satellite centre. Patients are made aware of the counselling services at the initial information evening which is attended by the counsellors and through written information given to them at stages of their treatment cycle.

90. Counselling is free and the number of sessions for each patient is unlimited.

Supervision and professional registration

91. The clinical inspector was informed that the counsellors are members of a professional body relevant to their discipline.

92. A comprehensive document “Operational Policy 2006” was seen by the inspection team.

93. The document stated clearly the key aims and objectives for the counselling team as well as the supervisors and counsellors details including their qualifications and membership of professional bodies.

94. They were each reported as receiving supervision from an external supervisor for a half day every month.

95. The counsellor interviewed reported that she felt integrated into the team and well supported by centre staff.

Counselling Audit

96. An audit for counselling for the period 1.04.2005 - 31.03.2006 was submitted with the inspection papers. The results included:

- Total number of hours provided: 26 hours per week for Barts and 10 for Norwich.

Waiting time to be seen by a counsellor:

- Appointments made by letter 2 weeks
- Appointments arranged over the phone/patient contact 1 week
- Urgent referrals 0-2 days.

- Number of referrals: 452
- Number of sessions given: 663
- Number of referrals who did not take up the offer of counselling: 139

Source of referrals:

- Fertility 295
- Gynae-Oncology 20
- Gynae 10
- Neurology 5

Location of counselling facilities

97. There are two rooms available for counselling sessions. Both were seen by the clinical inspector and considered to be satisfactory.

98. Counselling records are kept in a locked cabinet which can only be accessed by the counsellors. The cabinet is in a room secured by keypad lock.

Patient experience

Patient feedback

99. The centre collects its own patient feedback via a suggestion box. Suggestions are discussed at the senior management meetings and changes considered and implemented where appropriate.

100. Copies of patient questionnaires received by the HFEA were given to the Person Responsible and discussed in detail. The results are not included in the report as it appears that the questionnaire may have in some instances been used to express opinions not related to treatment at Barts.

101. The Person Responsible agreed to discuss the results within the team to try to identify areas of concern.

102. Two couples were interviewed on the day of the inspection. Both reported high levels of satisfaction with the centre staff and services. Both couples had been offered counselling and had been provided with contact details of the counsellors.

103. They had been made aware of how the side effects of treatments and of how to contact a member of the team out of clinic hours.

104. Neither of the couples had any negative comments to make about the centre. However they were not aware of the formal process to follow should they wish to make a complaint. This was discussed with the team during the feedback session and they will endeavour to ensure that all patients are made aware of the complaints procedure.

Patient information

105. Patient information submitted for the inspection was considered by the inspection team to be clear, concise and comprehensive. Patients interviewed on the day of the inspection reported a high level of satisfaction with the information they had received throughout their treatment cycle.

106. Patients are required to attend a two hour information session prior to commencing treatment. This is a group session where they have the opportunity to hear presentations and meet with members of the team.

Record keeping procedures

107. Ten patient files were reviewed on the day of the inspection and found to be satisfactory.

Three embryo transfer arrangements

108. The three embryo transfer log was seen by the scientific inspector. It was noted that a three embryo transfer had been performed in a patient who was under forty. This was discussed during the feedback session and the centre staff informed that this is a breach of the Code of Practice 8.20. The Person Responsible has since the inspection informed the executive that all relevant staff have been made aware of the circumstances of this breach and protocols have been amended.

Audit

Centre's own audit of stored material

109. The centre staff have performed an audit of stored material within the last twelve months. Embryos from one couple were in storage beyond the 5 year limit. The HFEA had been informed.

Spot check of tracking process for stored material

110. A spot check was performed in the presence of the scientific inspector. No anomalies were noted.

HFEA register

111. Operational Audit last visited the centre from 29th November - 1st December 2005. The summary of key points is as follows:

- There are still some weaknesses in the system for ensuring all licensed treatments are reported within the time requirements of Direction 1999/1. However the centre has taken significant steps to address the previous backlog in reporting which arose through the loss of two experienced staff members. They have recently appointed a specific individual with responsibility for ensuring all HFEA forms are completed accurately and returned within the statutory timescales.

- A statistically random sample of 51 IVF treatments was examined and it was found that 4 chargeable treatments were overdue and outstanding at the time of audit. Of 25 DI treatments examined three were overdue and outstanding at the time of the audit.

- The accuracy of 41 Registration, Treatment and Outcome forms was examined and 20 were found to have errors. A significant number of these errors related to donor insemination treatment forms where errors on donor numbers or DI treatment history were found.

The findings were discussed with members of the centre team and a return visit by audit will be necessary.

Clinical governance

112. The Nominal Licensee acts as a link between the centre team and the Trust's clinical governance structures.

Risk management

113. The centre's Person Responsible attends a quarterly risk management meeting with the Trust.

114. Staff interviewed on the day of the inspection were aware of the internal and external incident reporting procedures. The definition of what constituted an incident was discussed during the feedback session.

115. No incidents have been reported to the HFEA by the Person Responsible in the previous twelve month period.

Complaints

116. The previous Licence.Committee asked that the number of complaints received by the centre team provide a focus for this inspection.

117. The number of complaints received by the centre in the last 12 month period has reduced by 50% for the same period last year.

118. Previously a recurrent theme of complaints was the issue of communication between the centre and its patients. Patients interviewed on the day of the inspection were specifically asked about their experience of communication with the centre team and they informed the inspector that it was satisfactory.

119. Comprehensive protocols for administration and communication procedures were reviewed by the inspection team and found to be satisfactory.

120. The patients interviewed on the day of the inspection were not aware of the formal complaints procedure. This was discussed during the feedback session and will be addressed.

121. The complaints folder was seen by the inspection team. 13 complaints have been received at the centre and these have been resolved.

Breaches of the Code of Practice or Act

122. Two breaches of the Code of Practice were identified at the inspection:

- A three embryo transfer was performed on a woman who was under 40 years of age. Code of Practice 8.20
- Embryos were in store beyond the statutory storage period.

Compliance with previous conditions and recommendations

Conditions

There are no additional conditions on the centre's licence.

Key points for the Licence Committee

123. The inspection team supports the continuation of the centre's licence.

Issues

124. The inspection team would like to draw the following points to the attention of the licence committee:

- A new Person Responsible has been appointed since the last inspection.
- Previous Licence Committee requested that the team for this inspection focus on the centres arrangements for contacting patents regarding the Deceased Fathers Act and also on communication issues between the centre and its patients
- Following last years inspection an administrator was appointed to oversee the arrangements for contacting patients regarding the Deceased Fathers Act. The Person Responsible has, since the current inspection informed the executive that this process has been completed.
- Comprehensive protocols for administration and communication procedures were reviewed by the inspection team and found to be satisfactory.
- The number of complaints received by the centre in the last 12 month period has reduced by 50% for the same period last year.

125. The inspection team support the renewal of the centre's licence.

Appendix A The inspection team and staff interviewed

The inspection team

Janet Kirkland	HFEA Lead inspector and Chair
Dr Elliot Lawrence	HFEA Scientific inspector
Dr Neelam Sood	HFEA Clinical inspector

Centre staff interviewed

Amanda Tozer	Person responsible
several.centre staff	

Conflicts of interest

None declared.

Licence Committee Meeting

8 June 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Barts and the London Centre for Reproductive Medicine (0094)
Licence Renewal

Members:
Ivor Brecker – Chair
Suzi Leather, Lay Member
Chris Barratt, Scientific Director, Birmingham Women's Health Care Assisted Conception Unit

In Attendance:
Frances Clift, Legal Adviser
Marion Witton, Head of Inspection
Claudia Lally, Committee Secretary

Observing:
David Archard
Ruth Fasht

Conflicts 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 (53 pages)
- no papers were tabled.

1. The papers for this item were presented by Janet Kirkland, HFEA Inspector. Ms Kirkland informed the Committee that this centre was first licensed in 1992 and has a good history of regulatory compliance. The centre treats a mixture of self-funded and NHS patients. A previous Licence Committee requested that this renewal inspection focus on the requirement for the centre to contact patients about the implications of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (DFA), and general communication issues between the centre and patients. Ms Kirkland reported that the centre has now finished informing patients about the DFA, and has a comprehensive set of protocols in place covering all aspects of communication with patients.

2. Ms Kirkland reported that the centre had increased the number of treatment cycles being carried out but the inspection team had not gained the impression that the centre staff were under pressure.

3. Ms Kirkland also drew to the Committee's attention the fact that the centre had carried out a three embryo transfer to a woman under 40. This had resulted in a twin pregnancy. Ms Kirkland informed the Committee that the centre had now amended its protocols so do not anticipate a recurrence of this event. The Committee noted that the three embryo transfer had taken place on the basis of a consideration of the specific clinical situation of the patient. The Committee agreed to remind the centre of the guidance given in the Code of Practice:

- 8.20 In circumstances where women are using their own fresh or frozen eggs or embryos, centres are expected to ensure that:
  i) Women aged under 40 at the time of transfer receive no more than either two eggs or embryos in any one cycle, regardless of the procedure used.

The Committee also agreed to remind the centre that three embryo transfers will continue to be monitored at this and all other centres. They asked the Executive to make this issue a focus of the next inspection to the centre.

4. Ms Kirkland also reported that the inspection team found that the centre had stored some embryos beyond their statutory storage period. The Committee noted that this was a breach of the Human Fertilisation and Embryology Act 1990. Ms Kirkland informed the Committee that this was an isolated mistake by the centre and not the result of an inadequate system.

5. The Committee noted paragraph 111 of the inspection report which summarised the findings of a recent HFEA operational audit report. This report found that half of the registration, treatment and outcome forms examined by the audit team contained errors. Ms Kirkland informed the Committee that 15% of these errors had been categorised by the audit team as critical, and that some of these critical mistakes related to donor numbers as reported on treatment forms. These critical errors were noted by the Committee with concern. The Committee agreed that the following condition should be placed on the centres licence:

- The Person Responsible must put measures in place to ensure an immediate and substantial reduction of errors in registration, treatment and outcome forms.

The Committee also asked that this issue be another focus of the next inspection of the centre.

6. The Committee noted that the centre was conducting Welfare of the Child assessments which reflected HFEA policy prior to the introduction of the new guidance which was introduced in November 2005. The Committee agreed that the Person Responsible should satisfy herself that the centre is fulfilling the requirements set out in the new guidelines.

7. Ms Kirkland informed the Committee that the centre had a low risk score, placing it amongst the lowest scoring centres. The Committee decided to renew the centre's licence for a period of three years, subject to the above condition.

Signed……. … Date……..
Ivor Brecker (Chair)