Human Fertilisation and Embryology Authority

Name of Centre:	Assisted Reproduction and Gynaecology Centre
Document Type:	Report of an Interim Inspection
Date:	May 2005

Human Fertilisation and Embryology Authority

Report of an interim inspection at

The Assisted Reproduction and Gynaecology Centre

May 2005

Contents

Key facts about the centre

Centre name Assisted Reproduction and Gynaecology Centre

Centre address 13 Upper Wimpole Street
London
W1G 6LP

Centre number 0157

Person responsible Mr Mohammed Taranissi

Nominal licensee Mr Mohammed Taranissi

Activities of centre

		2004
Licensed treatment cycles	IVF ICSI PGS Egg Sharing GIFT ZIFT	No figures available.
Donor Insemination	Yes	
Unlicensed treatments	IUI	
Research	None	
Storage	Yes	

Focus of inspection General

Additional licence conditions One

Licence expires 30 June 2007

Summary

1. The centre has been licensed since 1995. It is a privately owned facility offering treatment generally on a private basis. Patients could be referred by the NHS. However funding arrangements would need to be agreed with the centre, prior to the start of treatment.

2. The centre has not complied with the condition imposed by the Licence Committee following the previous site visit. In addition recommendations made have not yet been implemented. The Person Responsible has been given the opportunity to provide an action plan to indicate how the condition and recommendations can be met. However this has not been received.

3. This report relates to an announced HFEA inspection. The site visit was undertaken on 31 March 2005. Paperwork was not submitted by the Person Responsible prior to the site visit and therefore nursing and laboratory protocols were reviewed at the time of the visit. The Person Responsible confirmed that clinical protocols remain unchanged from the previous visit.

4 A meeting has been held with the Person Responsible since the site visit when a copy of the draft report was shared. The Person Responsible was invited to comment upon the report and was requested to submit outcome data by Friday 6 May 2005. However this information has not been received.

5. On the day of site visit the centre was fully operational. Interviews were held with key members of staff and seven patients who were present for consultation on the day of the visit.

6. The centre is also registered with the Healthcare Commission and has worked towards meeting with the Care Standards Act 2000 and associated legislation. However it was noted at this site visit that some procedures in place did not always reflect the HFE Act and Code of Practice 6TH Edition. Examples included the management of incidents and complaints, the arrangements for the assessment of welfare of the child and the HFE (Deceased Fathers) Act which was introduced in 2003.

7. Patient areas were well presented. The centre is arranged over four floors. Three floors are currently being used as patient areas. There is no passenger lift at the centre and patients would need to have the ability to use the stairs to access the basement and first floor.

8. The centre has close links with centre 0206 in that some treatments are shared between the centres. Centre 0206 is located within walking distance of centre 0157. Mr Taranissi is Person Responsible for both centres.

Background to inspection

9. The report covers the period from February 2004 to March 2005.

10. The site visit took place on 31 March 2005 and lasted 9 hours.

11. During the course of inspection, seven patients were interviewed. Four patient questionnaires for Centre 0157 were also completed on the HFEA website. Outcomes of the discussions held and the completed questionnaires are included in this report.

12. The audit visit also took place at the time of the site visit.

13. The inspection report was reviewed by the centre in April 2005

The centre's context

14. Prior to the site visit, the HFEA liaised with the Person Responsible for several months to agree a suitable date for the visit. Relevant correspondence was sent to the Person Responsible on 26 October 2004, 23 December 2004, 7 January 2005, 2 February 2005, 11 February 2005, 18 February 2005 and 4 March 2005. Application forms were submitted for completion and the centre was requested to send information to the HFEA by 1 February 2005. The application for centre 0157 was received following the inspection during the meeting held on 22 April 2005.

15. During the meeting held with the Person Responsible on 22 April 2005, it was agreed that outcome data would be submitted to the HFEA. In addition the Person Responsible agreed to submit comments to the draft report together with an action plan proposing how the centre intends to meet with the condition and recommendations made following the previous site visit. A letter was sent to the Person Responsible on 29 April 2005 requesting this information by 6 May 2005. However to date this information has not been received.

16. Patients generally attend the centre for private treatment. However patients can be referred by the NHS once funding for assessment and treatment has been agreed with the centre. Patients are currently referred from Britain and overseas. The centre has confirmed that less than 5% of patients are referred from overseas.

17. There have been no changes to the premises since the last inspection and the HFEA have not received any notification regarding any changes to take place in the near future.

18. Opening hours at the clinic vary. Staff confirmed that the clinic is open on most days. Hours of work are varied to meet the needs of individual patients. During their interviews, staff said that their working hours are flexible and did

not consider that they were expected to work too many extra hours. The clinic can open each day. However weekend appointments are generally allocated to follow up patients treated during the week.

Type of work carried out

Licensed treatment

19. The centre carries out the following licensed treatments;

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

Satellite/transport arrangements

20. The centre does not have any satellite arrangements in place.

Staff

21. There has been little change in the staff group over a number of years. However since the previous inspection visit, there has been a change of doctor. The HFEA has not yet been notified of this change and Mr Taranissi confirmed that he would submit this information following the inspection. However this information has not been received. The remaining staff group remains unchanged.

22. The stable staff team facilitates continuity in care for patients.

23. Staff confirmed that they attend conferences and undertake both in house and external training. However there is a need to record training sessions attended to demonstrate the level of overall training undertaken at the centre. It was also recommended that a more planned approach be given to future training. The Person Responsible agreed that training could be linked with the appraisal process.

24. Staff appraisal takes place which is linked with pay. The Person Responsible has recently been involved in a review of his own performance

in line with General Medical Council (GMC) requirements. This is a requirement for all doctors.

Staffing profile

Person responsible	Mr Mohammed Taranissi.
Nominal licensee	Mr Mohammed Taranissi.
Accredited consultant	Mr Mohammed Taranissi.
Other medical staff	1
Embryologists	6
ICSI practitioner	6
Nursing staff	6 including the nurse co-ordinator
Independent counsellor	1
Complaints manager	Ms Elly Fincham

Professional registration and continuing professional development (CPD)

25. Recruitment procedures have been introduced to ensure that staff are fully vetted prior to their recruitment. Staff files were sampled which demonstrated that proof of identity, references, proof of qualifications and an interview process takes place prior to staff being employed. In addition all staff have had enhanced Criminal Record Bureau (CRB) checks undertaken.

26. Anaesthetists have been granted practising privileges and relevant contracts are in place. This was confirmed by the procedure titled “Practicing Privileges” dated 1 July 2004.

27. Nursing staff are registered with the Nursing and Midwifery Council, doctors with the General Medical Council and Embryologists are registered with the Health Professions Council. The registration of staff is checked annually.

28. Staff files confirmed that new staff undertake induction training. A mentorship scheme is operated where new staff will work alongside a member or staff who undertakes a similar role.

29. Staff confirmed that training takes place in house. In addition staff, attend external conferences and seminars. The Person Responsible will pay for training and enable staff to take time off to attend training sessions.

30. A system of audit has recently been introduced. This has included a recent audit of patient information.

31. Short staff meetings are held as necessary with formal meetings taking place every three months. Most are minuted with a copy of the minutes made available during the course of inspection.

32. The Person Responsible is aware of individual staff performance. However formal performance systems are yet to be put into place.

The premises, equipment and other facilities

Premises

33. The centre is arranged over four floors. Three floors are currently used by patients. The fourth floor is used by staff and to store records.

34. All patient areas are spacious well ventilated and comfortably furnished.

35. The entrance is located on the ground floor which includes administration offices, a reception area and a waiting room for patients. A selection of toys, are available in the waiting room for patients who bring their children. The centre's licence is displayed in the reception area.

36. The first floor accommodates two large rooms where patients are seen for consultation and medical examination. The rooms are connected by an adjoining door which when opened enable the room to be used as a meeting room. A men's production room is also located on this floor.

37. The procedure room, recovery room, changing rooms and laboratories are situated in the basement.

38. The laboratory is spacious and well equipped. Back up systems are in place for critical equipment. Current systems are soon to be enhanced by the installation of alarms on dewars. All laboratory equipment is regularly maintained and this is overseen by the Senior Embryologist.

39. The laboratory is located alongside the procedure room.

40. WC's are available on each floor of the centre.

41. The centre is not able to treat patients who are unable to use the stairs as there is no passenger lift. In addition there are no disabled WC facilities.

42. At the time of inspection, patients commented positively regarding the environment. A comment received was "the building is welcoming with comfy sofas and magazines and more like home than a clinic".

Equipment

43. Equipment is in use at the centre which is regularly maintained and replaced as necessary. Maintenance contracts are in place with external contractors to ensure that equipment is kept in good order. General maintenance contracts are overseen by the nurse co-ordinator whilst maintenance

contracts for specialist laboratory equipment are overseen by the Senior Embryologist.

44. Where daily checks are needed on equipment, a record of checks was seen to be made. This included the temperature of the refrigerator used to store medicines and the incubators in the laboratory.

Security

45. Visitors gain access to the building by ringing the bell and therefore staff are aware of who enters and leaves the building. Keypads control access to the laboratory areas.

46. When closed, the building is locked.

Confidentiality

47. It was evident through discussions with staff that there is a high level of general awareness regarding patient confidentiality.

48. Patient records are stored in filing cabinets located on the first, second and third floors. Not all rooms where records are being stored are being locked.

49. A men's production room is located on the first floor which is suitably furnished and equipped. The room incorporates a WC and a bidet.

Cryostore facilities, oxygen and dewar alarms

50. There are secure storage facilities for gametes and embryos. Access is restricted by the use of a coded lock.

51. Material for storage is being screened for Hepatitis B, Hepatitis C and HIV. Unscreened material is also being stored which is being kept separately from screened samples.

52. Dewars are not yet alarmed. However the Person Responsible confirmed that this is to be undertaken within two weeks of this inspection visit. A low oxygen alarm is in place in the room used to store dewars.

Emergency facilities

53. The centre has a resuscitation trolley located in the basement where treatments take place. The equipment meets with guidelines set by the Resuscitation Council (UK). There is a system in place whereby resuscitation equipment is checked daily with a record kept of each check.

54. Staff, are on duty at all times who have undertaken basic resuscitation training. In addition when treatments require sedation, an anaesthetist is present who has undertaken advanced life support training.

55. Should a patient require ongoing emergency care whilst present in the centre, emergency services would be called to transfer the patient to hospital.

56. Where complications may result from treatment/s carried out, the Person Responsible can admit patients privately either to the Portland Hospital or the Wellington Hospital in London. Alternatively patients would be admitted to a local NHS hospital where the Person Responsible would liaise with the medical team. For patients from overseas, telephone advice is provided and where necessary liaison with the medical team.

57. In discussions, patients confirmed that they are given emergency contact details for the Person Responsible. One patient confirmed that she had contacted the Person Responsible "out of hours" and had received a good response.

Clinical, nursing and laboratory procedures

Clinical

58. The Person Responsible confirmed that clinical protocols had not changed since the previous inspection visit.

59. However existing protocols submitted to the HFEA in 2004 have been reviewed. Not all protocols were available and further protocols are requested including those in relation to ZIFT. In addition, protocols need to be version controlled and include a review date.

Nursing

60. Nursing protocols have been developed which had recently been updated. Examples were seen where protocols had been linked to current good practice guidance. These included protocols for infection control and resuscitation. However other protocols were brief and needed to include further information. An example of this was the protocol relating to consent. Most protocols were dated and included a review date. There is a system in place whereby staff, sign to confirm that they have read and understood the contents of the protocols.

61. Nurses interviewed confirmed that they can attend external courses which are funded by the centre. In addition nursing staff are involved in an appraisal process. The need for a more planned approach to training, linked with the appraisal process was discussed with the Person Responsible.

Laboratory

62. Laboratory protocols are in place which are dated 2004. The protocols are version controlled, evidence based and those sampled reflected current laboratory practice/s. However the protocols are due to be reviewed.

63. There are procedures in place for cleaning, filling and securing vessels.

64. Procedures are also in place regarding freezing, thawing and handling of contaminated samples.

65. The centre has relevant procedures in place for witnessing which are recorded.

Procedures for assessing clients and for assessing and screening donors

Welfare of the child

66. On each file seen, a check sheet had been completed by the patient, which included their consent to contact their GP regarding Welfare of the Child issues. In addition a family history was seen to be recorded in patient notes, which was comprehensive. Inspectors were told that where the Person Responsible considers that there may be a risk to the welfare of any child or children born as a result of treatment, the GP would be contacted for further information. However where there is no perceived risk, welfare of the child assessments would not be pursued. This was confirmed by the Person Responsible when interviewed.

Ethics committee

67. The centre does not have access to an ethics committee. Discussions were held with the Person Responsible who said that there had never been any issues which needed to be shared with a committee. It was also confirmed that the centre does not treat single women or single sex couples. Treatments using egg donation are limited and levels of screening including pre implantation genetic screening have meant that cases have not needed to be referred to an ethics committee.

68. Multi disciplinary meetings are held regularly in the clinic where patients are reviewed individually and any issues could be raised.

Assessing and screening donors

69. The centre does not actively recruit donors. However should a patient wish to be treated with gametes of a known donor, the Person Responsible said that this would be considered. Protocols need to be developed which include how the centre assesses and screens potential donors.

70. Documentation developed by the HFEA is given to potential donors. It is however recommended that the clinic develop its own literature to describe current practices at the centre.

Counselling process and facilities

Counselling protocols

71. Counselling is available to all patients considering fertility treatment, during their treatment/s and following their treatment at the centre. The Counsellor is not employed by the centre and therefore provides an independent service to patients.

72. All patients receive an information pack once referred which includes basic information regarding the counselling service on offer. Patients are also advised of the service during their first consultation. Leaflets regarding this service are also available in the waiting room and a guide has been prepared which is given to patients. The guide includes contact information for patients.

73. Nursing staff confirmed that counselling is particularly recommended to patients considering treatments using donor sperm or eggs and also to donors.

74. The guide advises patients that a separate fee is charged for counselling sessions. Each session lasts for one hour.

Supervision and professional registration

75. The Person Responsible confirmed that referrals have been made to the same Counsellor since the centre opened in 1995. Discussions were held regarding the need for the centre to have the ability to demonstrate the qualifications and ongoing training of the Counsellor together with details of her membership of an appropriate professional body.

Counselling audit

76. It was made a recommendation following the inspection on 11 February 2004 that an audit needed to be undertaken with regards to the counselling provision to meet with 7.6 and 7.10 of the HFEA Code of Practice, Sixth Edition. The Person Responsible confirmed his satisfaction with the service provided. However an audit of the service has not yet been undertaken.

Location of counselling facilities

77. Counselling currently takes place off site. It is understood that protocols are not kept on the premises. However arrangements have been made for one session each week to be held in the centre from 4 April 2005 when protocols will be available onsite.

Patient experience

Patient feedback

78. Patient feedback was obtained during interviews at the time of the site visit. In addition four questionnaires had been completed on the HFEA website. Comments were positive. Patients said that they were "treated as individuals" and said that their treatments were "tailored around their personal needs".

79. Patients spoken with at the time of inspection were complimentary regarding the care and personal attention given by Mr Taranissi and also the friendliness of the staff.

80. Additional comments obtained from patient questionnaires were that the clinic can be "very busy and can sometimes appear to be disorganised at times although in reality they are highly organised". "It was reassuring to be able to talk to doctors 24/7" "Staff were friendly and approachable". "Excellent standard of personalised, individual care". A further comment was received "the clinic can be very busy which means can lead to a delay in being seen".

81. One questionnaire included comments that the welfare of the child requirement is ridiculous.

Patient information

82. All patients referred to the clinic receive a pack of information. This includes a Patient Information Booklet which contains general information and additional leaflets.

83. The booklet describes the patient journey through the clinic which includes, the referral process, the first consultation and general fertility services provided.

84. The booklet also gives basic information regarding the internal complaints process.

85. A leaflet titled "New Patients-What to Expect" has been developed which describes the investigations and procedures which may follow the initial consultation.

86. A separate leaflet describes the complications of assisted reproduction treatment. This includes severe hyper stimulation syndrome, multiple pregnancy and ectopic pregnancy.

87. Instruction sheets have also been developed for patients regarding individual treatments. Samples seen included Instructions Following Vaginal Ultrasound Egg Collection and After the Embryo Transfer.

88. Patient's also receive information regarding success rates which are divided into live birth rate per embryo transfer for all ages and live birth rate per embryo for patients under 38 years.

89. A price list for treatments has also been developed. Investigations are tailored to individual patients and as a result cost can deviate from the price list. However it was reported that such deviations are discussed with patients in advance. The price list did not include the cost of immunology services.

90. Gamete donation is a rare occurrence at the centre. HFEA information is given to patients regarding the use of donated gametes where necessary.

91. Consent is discussed individually with patients. There was no additional information for patients in the patient information guide.

92. Not all patient information is version controlled and it is recommended that this system is put into place.

93. Patients are given the contact telephone number for the Person Responsible which includes and out of hours' telephone number should any advice be needed.

94. A procedure has been developed titled "Information for Patients". This confirms that information can be provided in English, Arabic and French.

Record keeping procedures

95. 30 sets of patient records were reviewed at the time of inspection. Since the patient journey may be shared between centres 0157 and 0206 a cross section of files were chosen which incorporated patients attending for treatment at both centres. Of the patient records sampled, nine included the part of the consent form which should be retained by the patient. 13 errors were noted in the patient notes sampled. In other respects the notes were accurate.

Treatment type	Error	Breach of Code reference	Number of errors
ICSI	Consent form not signed	HFE Act Schedule 3 Para 6.	1
Egg donor, ICSI,	"No" boxes not completed.	HFE Act Schedule 3 Para 2(2).	4
Storage of embryos	Wishes following death not completed	Code Of Practice 6th Ed 6.24.	1
Storage of embryos	5 and 10 year storage ticked.	HFE Act Schedule 3 Para 2(2).	1

ICSI	Welfare of the child assessment form not completed.	HFE Act 1990 Section 13.	1
Assisted hatching	Photocopied consents used. 006 information not present.	HFE Act Schedule 3 Para 6.	1
ICSI	Storage section not completed	HFE Act Schedule 3 Para 2(2).	3
Storage of embryos	Agreement to store embryos for 10 years but no HFEA (96)8 form completed	HFE (Statutory Storage Period) Regulations 1991.	1

Data analysis

96. Data was not submitted by the centre prior to this inspection**.**

Three embryo transfer arrangements

97. Between January and June 2004 of 199 patients treated, 35 patients had received three embryo transfers. Since March 2004, there have been no three embryo transfers.

98. The three embryo log could not be seen at the time of the inspection as the record was locked away. The centre has been asked to submit a copy of the log to the HFEA. However this information has not been received.

Audit

Centre's own audit of stored material

99. Annual reviews of stored gametes take place. In addition each dewar has sheets attached which record the names of cryo samples in place. Names are ticked when the audit is undertaken and the list is then cross referenced against a central file in addition to the contents of the dewar. There were no discrepancies noted.

Spot check of tracking process for stored material

100. An audit was undertaken on randomly chosen samples including 4 sperm samples from dewar to file and file to dewar and for 4 embryo samples from dewar to file and file to dewar. There were no discrepancies noted.

HFEA register

101. The HFEA audit was undertaken at the time of the site visit and took two days to complete. The audit highlighted a need to place greater emphasis on ensuring that HFEA forms are completed and submitted to the HFEA within the relevant timescales.

102. Without exception treatments were being reported accurately to the HFEA. However, 7% of treatment forms had not been received by the HFEA.

103. 24% of the treatments reviewed were reported late to the HFEA.

104. A sample of HFEA registration, IVF treatment and outcome forms as completed by the centre and compared to the patient medical records were reviewed to assess their accuracy. 20 forms were reviewed with no errors identified out of 251 fields.

Clinical governance

105. The centre has no links with the NHS and therefore relies upon it own internal clinical governance arrangements. A system of audit has recently been introduced which is ongoing. An audit on patient information had taken place with one change noted as a result of the audit.

106. Regular staff meetings take place where issues relating to practice can be discussed. In addition to multidisciplinary meetings, departmental meetings also take place. Formal minutes are kept of meetings which are kept centrally in a clinical governance file.

Risk management

107. Risk management systems are in place for the management of the building. Risk in relation to treatments are considered individually with patients and recorded in patient notes.

108. There is a procedure in place for the management of incidents. However this does not include information in relation to reporting incidents to the HFEA. The procedure needs to be updated to include this. Staff interviewed could not recall an incident that had occurred which needed to be reported to the HFEA.

109. Staff were aware of the alert system initiated by the HFEA. Outcome/s of any incidents or alerts would be discussed during staff meetings as they arise.

Complaints

110. There is a complaints procedure in place which does not include complaints information in relation to the HFEA. This procedure needs to be expanded to include this information. Patients receive brief information regarding complaints in the Information Guide. However this does not include all avenues for complaint. In addition there was no procedure displayed in patient areas in the centre.

111. At the time of inspection it was understood that there had been no complaints received by the centre since the previous visit. However the application received since the inspection highlights two complaints with no issues outstanding.

112. Whilst evidence of staff training in complaints was not seen at this inspection, there is a system in place whereby staff sign to confirm that they have read and understood the information.

Breaches of the Code of Practice or Act

113. The centre needs to develop a system whereby the patients GP is contacted in each case regarding welfare of the child issues.
HFE Act Section 13(5), HFEA Code of Practice 6th Edition 3.3.

114. The centre needs to have the ability to demonstrate the qualifications and experience of the counsellor. In addition an audit of the counselling provision needs to be undertaken.
HFE Act Section 17(1)(a), HFEA Code of Practice 6th Edition 1.9

115. The centre should place a lock directly on the doors to rooms where records are stored.
HFEA Code of Practice 6TH Edition 11.13.

116. Dewars need to be alarmed. (Arrangements have been made for this to be undertaken. The person responsible should write to the HFEA when this work has been completed).
HFEA Code OF Practice 6th Edition 9.8.

117. The complaint procedure needs to be expanded to include all avenues for complaint, including the HFEA. A copy of the procedure needs to be displayed in a patient area such as the waiting room.
HFEA Code of Practice 6th Edition 13.1; 13.4

118. The centre needs to develop a procedure regarding the management of incident reporting which meets with the requirements of the HFEA,
HFEA Code of Practice 6TH Edition 2.23

119. The centre needs to develop systems to ensure compliance with the HFEA (Deceased Fathers) Act 2003.
HFEA (Deceased Fathers) Act 2003, HFEA Code of Practice 6th Edition 6.24; 6.25

120. A more formal approach needs to be given to the planning of staff training.
HFEA Code of Practice 6th Edition 1.4(i).

121. The Person Responsible must ensure that the centre complies with all the conditions on its licence.
HFEA Code of Practice 6th Edition 1.4(v).

Compliance with previous conditions and recommendations

Conditions

122. There was one condition on the previous licence.

Conditions	***Adopted by centre (Y/N)***	***Comment***
The centre must submit dated and signed clinical protocols for assisted hatching (mechanical) and ZIFT if you wish to continue to be licensed for treatment. Patient information for Zift must also be submitted.	NO	Not met.

Recommendations

123. The licence committee made 6 previous recommendations. They are listed below along with the centre's response.

Recommendation	***Adopted by centre (Y/N)***	***Comment***
1. Your centre should formalise and submit to HFEA written protocols regarding the audit of samples and required consents.	No	Not met
2. Your centre should routinely contact all GP's regarding welfare of the child in accordance with Section 3.20 of the HFEA Code of Practice 6th Edition.	No	Not met

3. Your centre should seriously consider separating the roles of Person Responsible Nominal Licencee for the protection of patient's interests should the person responsible not be able to fulfil his duties under Section 17 of the HFE Act. (Chair letter CH (01)01.	No	No action taken.
4. Your centre should place a lock directly on the doors of the rooms holding patient records and ensure records are kept secure, with access to them restricted to those who need to see them.	NO	No action taken.
5. The independent counsellor for your centre should carry out an audit of the counselling provision for the Centre's patients over the past 12 months and provide a copy to the HFEA.	NO	No action taken.
6. Your centre should review and revise their Patient information in the light of the inspection teams observations; • Information on the storage of sperm does not detail how long the sperm may be stored for nor how long the period can be extended in eligible cases. Patients are not reminded to remain in contact with the centre in order to update their wishes concerning the future of stored samples. • Information on the storage of embryos gives information on how long the embryos may be stored for and that the storage period can be extended in eligible cases. Patients are given a copy of the HFEA leaflet on embryo storage but are not reminded in the centres literature to remain in contact in order to update their wishes concerning the future of their stored embryos. It could be made clearer to patients that their embryos will be disgarded when the consent period has expired. • The complaint information invites patients to contact the Nurse Co coordinator but does not include a contact name. The complaints process does not appear to be	No	No action taken.

	explained to patients. However the centre did provide a copy of the patient questionnaire to be returned to the named Nurse Co coordinator.		

Key points for the Licence Committee

Issues

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

125. The centre has a high success rate.

126. The centre has not met with the condition and six recommendations made following the previous site visit.

127. As a result of this site visit there are two breaches of the HFE Act 1990, a breach of the HFE (Deceased Fathers) Act 2003 and six breaches of the Code of Practice 6th Edition.

128. As a result of the audit undertaken the need for completion and submission of HFEA forms was highlighted.

Recommendation

129. The inspection team supports the continuation of the centre's licence. However the Licence Committee will need to decide what if any regulatory action will need to be taken regarding the issues outstanding in this and the previous inspection report/s.

Appendix A The inspection team and staff interviewed

The inspection team

List the inspectors in alphabetical order. If you include a title for one person ensure you include it for all to maintain consistency.

Sandy Mather	Head of Inspection, HFEA
Christine Williamson	Chair, Senior Regulatory Manager, HFEA
Stephen Lynch	Scientific inspector
Helen Kendrew	Nursing inspector

Centre staff involved in interviews and discussions with the inspection team

1	Person responsible and Nominal Licencee
1	Nurse Co coordinator
1	Nurse
1	Embryologist
2	Administrators

Conflicts of interest

None declared.

Human Fertilisation and Embryology Authority

Centre Name : Assisted Reproduction and Gynaecology Centre

Document Type: Licence Committee Minutes

Date : May 2005

Licence Committee Meeting

25 May 2005
21 Bloomsbury Street London WC1B 3HF

MINUTES item 3

Centre: Assisted Reproduction and Gynaecology Centre (0157)
Interim Inspection

Members:
Emily Jackson, Lay Member – Chair
Sharmila Nebhrajani, Lay Member
Ivor Brecker, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary

In Attendance:
Trish Davies, Director of Regulation
Frances Clift, Legal Adviser
Stephanie Sullivan, Head of Clinical Governance and Patient Safety
Christine Williamson, Senior Regulatory Manager
Claudia Lally, Secretary to the Committee

Providing Legal Advice:
Graham Miles, Morgan Cole Solicitors

Conflicts of Interest: members of the Committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (46 pages)
- no papers were tabled.

1. The papers were presented by Christine Williamson who informed the Committee that the interim inspection for this centre took place on 31 March. The pre-visit paperwork from the centre was received on the 22 April. This paperwork was incomplete, and in particular did not contain the centre's protocols or data on treatment outcomes. The centre had also been asked to submit its three embryo transfer log-book but has not done so.

2. Ms Williamson drew the Committee's attention to the failure of the centre to comply with the Chair's Letter CH(03)06. She explained that the centre had been failing to make patients aware of the implications of the Human Fertilisation and Embryology (Deceased Fathers) Act 2003. The Nurse Coordinator had told the inspection team that she had not been informed about the requirements

contained in Chair's letter CH(03)06, which sets out the responsibilities of centres in relation to this Act. The Nurse Coordinator undertook to comply with these requirements after she was made aware of them. Ms Williamson also informed the Committee that the inspection team identified a number of concerns with respect to the provision of counselling, most notably the fact that there was no proof available of the counsellor's qualifications. In addition, the centre had not carried out an audit of counselling provision and submitted the results to the Authority. Ms Williamson informed the Committee that the centre will soon be setting up a Practicing Privileges contract with the counsellor, at which point the qualifications of the counsellor will be specified.

3. Ms Williamson drew the Committee's attention to the centre's lack of progress in complying with the condition which was placed on their licence by a Licence Committee on 10 June 2004, and with the six recommendations made by that Committee. The Committee considered the centre's lack of compliance with the condition which required it to submit clinical protocols for assisted hatching and ZIFT. Graham Miles advised the Committee that there was a duty of the Person Responsible under section 17(1) (e) of the Human Fertilisation and Embryology Act 1990 to secure that the conditions of the licence are complied with. Breach of this duty entitled the Committee to vary the licence under section 18(3) of the Act. The Committee therefore decided to make a proposal to vary the centre's licence to remove the two activities: ZIFT and mechanical assisted hatching. The Committee agreed, however, that these two activities should not be removed from the centre's licence if the Person Responsible confirms to the Authority that he wishes them to remain on his licence, and submits the documentation required under the condition.

4. The Committee noted that the centre had not complied with the previous recommendation that the centre should formalise and submit to the Authority protocols requiring the audit of samples and consents.

5. The Committee noted paragraph 66 of the inspection report, which states that the Person Responsible caries out his own assessment of the welfare of any child to be born as a result of treatment. This was welcomed by the Committee, who nevertheless agreed that the welfare of the child assessment should be carried out in compliance with the provisions of part 3 of the Code of Practice, in particular part 3.20 (iii) under which centres are expected to contact the GPs of both partners when assessing all prospective patients.

6. The Committee noted that the centre has not taken action to separate the roles of Person Responsible and Nominal Licensee. Ms Williamson confirmed that the Person Responsible had agreed to consider this course of action, but had not approached the Authority to arrange it. The Committee accepted that there might be reasons why the separation of these roles would be impractical for this centre.

7. The Committee considered the failure of the centre to comply with the recommendation that it installs a lock on the door of the rooms in which patient information is kept. Ms Williamson informed the Committee that on the day of the inspection there had been a number of painters on the premises who might have been able to gain access to these rooms. The Committee agreed that the installation of locks on these doors would be an important safeguard against a breach of confidentiality, particularly on occasions when there are non staff-members in the centre. The Committee therefore agreed to advise the centre that it should comply with Part 11.14 of the Code of Practice and install locks on the rooms in which records are kept to ensure the security and confidentiality of patient records. The Committee advised that this should be done within three months of the date of this meeting.

8. The Committee considered the centre's failure to comply with the request to produce an audit of counselling provision at the centre. The Committee noted that this audit is requested of all centres, and agreed to remind the Person Responsible that the centre should carry out such an audit as soon as practicable and submit the results to the Authority.

9. The Committee considered the centre's lack of compliance with the request to revise its patient information. The requested revisions are set out under point 6 of paragraph 123 of the inspection report. The Committee expressed concern about the fact that the revisions to patient information have not been made by the centre. In particular, the Committee noted that the information about how to make a complaint invites patients to contact the Nurse Coordinator but does not include a contact name. The Committee agreed that the attention of the Person Responsible should be drawn to part 13.4 of the Code of Practice, which specifically mentions the importance of advising patients of the name of the complaints officer. The Committee also considered the need for the centre to include information on the statutory storage period for sperm. The Committee agreed that knowledge of the statutory storage period for sperm is necessary for a patient to give effective consent to the storage of sperm under the provisions of Schedule 3.2(2) of the Human Fertilisation and Embryology Act 1990. The Committee agreed that the centre should be advised to implement the required changes in patient information within three months of the date of this Committee meeting.

10. The Committee noted paragraph 108 of the inspection report which states that there is no procedure in place for the reporting of incidents to the Authority. The Committee agreed that the attention of the Person Responsible should be drawn to part 2.23 of the Code of Practice, which states:

> Each treatment centre is expected to have a written policy and procedure for dealing with adverse incidents. Centres must report all adverse incidents occurring at the treatment centre to the HFEA by telephone

within 12 working hours of the identification of the incident and submit and Incident Report Form within 24 working hours.

The Committee agreed that the centre should be advised to amend its incident procedure to include this information within three months of the date of this meeting.

11. The Committee agreed to advise the centre that for all current patients it should comply with immediate effect with the requirements set out in Chair's Letter (03)06, and that all men who have made provision for posthumous conception should be contacted by the centre and informed of the additional consent required under the Human Fertilisation and Embryology Act 1990 (Deceased Fathers Act) 2003 within the next three months.

12. The Committee noted that the centre had not submitted treatment outcomes or other data requested by the Authority, and in particular had not complied with the request to submit its log book in which three embryo transfers were recorded. The Committee agreed to request that the centre submits this data forthwith.

Signed…… … Date……..
Emily Jackson (Chair)