Interim Inspection Report

The Agora Gynaecology & Fertility Centre
0254

Date of Inspection: 5 August 2009
Date of Licence Committee: 16 December 2009

Centre Details

Person Responsible	Dr Carol Gilling-Smith
Nominal Licensee	Mr Hossam Abdulla
Centre name	The Agora Gynaecology & Fertility Centre
Centre number	0254
Centre address	The Agora, Ellen Street, Hove, BN3 3LN
Type of inspection	Interim
Inspector(s)	Paula Nolan (Chair, HFEA Executive)
	Stephen Lynch (HFEA Executive)
	Ian Peacock (HFEA Executive observing)
Fee paid	N/A – interim inspection
Licence expiry date	31 January 2011
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 5 August 2009.

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

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

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

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

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Agora Gynaecology & Fertility Centre is a private centre that treats both self funded and NHS patients. 227 cycles of IVF/ICSI/FET and DI were provided in 2008. The centre does not provide treatment with donated eggs nor does it recruit sperm donors. However the centre does treat recipients with known donors and hopes to start up a sperm donor programme (for Agora patients only). The centre now has an NHS contract with Brighton Primary Care Trust for follicle tracking and IUI and is currently finalising a contract for IVF/ICSI cycles.

The centre is open 9am to 5.30pm, Monday to Friday and is also open on Saturday from 9am to 1pm.

The centre is currently awaiting planning approval to take over the lease of the third floor West of the Agora building in addition to the existing premises on the third floor East. This extra space would provide a larger meeting room for staff, a second administration office, a dedicated counselling room and two further consulting rooms. The existing meeting room would then be converted to a second recovery bay in the existing premises to accommodate the increase in patient cycle numbers anticipated over the next three years.

Currently the dewars are located in the existing premises on the third floor East. The PR is in the process of applying to vary the licence to move the dewars to a secure storage facility located on the ground floor of the building.

The Person Responsible has been in post since February 2007 and is registered with the General Medical Council (GMC) on the Obstetric and Gynaecology specialist register.

Activities of the Centre[1] for the time period from 1 March 2008 to 30 April 2009

In vitro fertilisation (IVF)	91
Intracytoplasmic sperm injection (ICSI)	126
Frozen embryo transfer (FET)	40
Intra uterine insemination (IUI)[2]	303
Donor insemination (DI)	34
Storage gametes/embryos	Yes

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

[2] This data is for the time period 1 January 2008 to 31 December 2008.

Summary for Licence Committee

At inspection the PR was found to be practicing at a suitable standard compliant with the requirements of S.17 of the HFE Act 1990. However, she has not completed unit two of the HFEA Person Responsible Entry Programme.

Based on the evidence seen on inspection the inspectorate concluded that no improvements, with relation to the requirements of the Code of Practice, are required in the areas of quality of service and information. Patients report satisfaction with the service they receive. Some improvements are recommended in the areas of organisation, premises and equipment and laboratory and clinical processes. In particular, improvements should be considered relating to the following aspects of the centre's practice:

- The PR to complete the Person Responsible Entry Programme
- Monitoring air quality
- Participating in inter- centre or inter-laboratory comparisons
- Ensuring that the counsellor notes (storage) and premises are complaint with Code of Practice (7th Edition) guidance

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

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service	✓		
3. Premises and Equipment		✓	
4. Information	✓		
5. Laboratory and clinical processes		✓	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The PR has not completed unit two of the Person Responsible Entry Programme (PREP).	The PR should complete the PREP in compliance with Standard .4.1.5 (Code of Practice 7th Edition).	Before Licence committee on 3 December 2009.
The centre does not participate in inter-centre or inter-laboratory comparisons. **This was mentioned in the previous inspection**	To comply with Standard 9.2.6 (Code of Practice 7th Edition) the PR shall arrange for the centre to participate in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality	Within six months.

report.	assessment schemes) and by other external bodies. The results of these comparisons should be evaluated and documented and relevant findings be used to improve the service.	
The centre could not provide evidence of the grade of air quality in the areas where gametes and embryos are processed.	To comply with Licence Condition A.10.19 and G.9.4.3. to G.9.4.7. The PR should ensure that the processing of gametes and embryos while exposed to the environment must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross contamination between donations. To achieve this, such gametes and embryos must be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1 and Directive 2003/94/EC. The effectiveness of these measures must be annotated and monitored.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
The centre needs to ensure that the air quality is regularly monitored.	The PR is reminded to consider the following guidance for the procurement, processing, storage and handling of gametes and embryos. Wherever practical, the centre should carry out procedures involving the processing of gametes or embryos in an environment with air quality of at least Grade C in the critical work area. The centre should strive to maintain a background environment of Grade D air quality in laboratories in which gametes or embryos are processed. (Code of Practice G.9.4.3) Where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result. (Code of Practice G.9.4.5) Air quality monitoring should be used as a routine	Immediately.

	measure of quality assurance (for example, through particle counts or the use of settle plates, keeping a record of any cultures observed). (Code of Practice G.9.4.6) Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, keeping a record of any cultures observed). G.9.4.6. The air quality validation process should include documentation of culture conditions, temperature mapping and use of control charts to predict effects of any change in procedures. (Code of Practice G.9.4.7)	
The counsellor stores counselling notes and sees patients off site at his consulting rooms.	As the counsellor stores counselling notes and sees patients in his consulting rooms the PR should visit the premises and carry out a risk assessment to ensure: • All counselling notes are held securely and confidentially (Code of Practice, 7th Edition, A.10.31, S.7.2, G.10.31, G.7.2, G.7.4). • The facilities are provided in quiet, comfortable, private and confidential surroundings (Code of Practice, 7th Edition, G.7.2, G.7.4 and S.6.3.5, G1.4.1).	At PR's discretion.

Recommendations

Area for improvement	Action required	Time scale
None	None	n/a

Changes/ improvements since last inspection

Recommendations	Action taken since last inspection
Two storage dewars within the cryostore were seen at inspection to not be alarmed. Staff reported that these had been ordered but had not arrived. Evidence was provided post inspection that this had been a delay on the part of the supplier	Following the last inspection the PR advised the HFEA that the two storage dewars within the cryostore that were not alarmed at the time of inspection were alarmed on the next working day 2.9.07. The alarms had been ordered on 2.8.07 and the company providing the alarms admitted they had delivered the alarms with considerable delay. The Lead Inspector was provided with the relevant correspondence.

During an audit of the patient notes, it was evidenced that not all witnessing steps had been completed in accordance with the requirements of the Code of Practice Version 7 or Witnessing Directions.	Following the last inspection the PR advised the HFEA that all steps in their laboratory are now witnessed irrespective of the circumstances. The centre has introduced a witnessing step during the disposal of embryos.
Ensuring patient privacy at the main reception desk.	Following the last inspection the PR advised the HFEA that all calls of a sensitive nature are passed from the front reception desk to the back office to be dealt with by other staff so that conversations cannot be heard by other patients in the waiting room. Further to this the patients account manager is now located in a separate office near the waiting room so that payment queries can be conducted in privacy.
Although evidence was provided during the inspection that records of traceability were maintained, it was noted that a procedure to document this requirement was not in place. It was recommended therefore that a policy be documented.	Following the last inspection the PR advised the HFEA that a traceability SOP is currently being written.
To establish links with the Lister Hospital fertility unit in London for conducting external reviews of their current practice.	Following the last inspection the PR advised the HFEA that the centre is the process of establishing a link with the Lister Hospital Fertility Clinic to allow external review of our clinical and laboratory practice. On inspection the PR confirmed that this had not yet been set up.
Staffing levels within the Embryology and Nursing Departments to be monitored and increased in accordance with requirements.	Following the last inspection the PR advised the HFEA that they have in the past and continue to monitor staffing levels to ensure these are matched to ongoing and predicted activity.

Additional licence conditions and actions taken by centre since last inspection

N/A

Report of inspection findings

1.Organisation

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

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

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

Areas of firm compliance
Documentation submitted for inspection, including an organisational chart showing key responsibilities and lines of accountability was reviewed by the inspection team and considered to be appropriate. The Person Responsible (PR) has implemented most changes as recommended in the report of the previous inspection. The premises appeared suitably equipped and the PR reported that she is confident that the unit has sufficient staff with relevant expertise. Processes are in place for the identification, notification and investigation of incidents. The centre's complaints log was reviewed by the inspection team and evidence of actions taken to resolve complaints were noted. Patients are provided with an out of hours emergency phone number. The centre has a service level agreement with the local NHS hospital for emergency referrals. The centre also has a formal contingency arrangement with The Lister Fertility Clinic (centre no 0006) who will take over the care of patients who have started treatment and the responsibility for stored samples in the event of service failure. Third party agreements are in place and were made available to the inspection team to review. A sample of agreements were reviewed and found to be compliant with HFEA guidelines. Weekly team meetings are also held to discuss practice related issues. A sample of minutes were made available to the inspection team. Issues including the annual audit plan (internal and external), customer satisfaction and feedback, infection control, laboratory quality control and staff suggestions were discussed. The HFEA finance department report that the centre takes an average of 24 days to pay invoices.

Areas for improvement
While the PR is considered appropriately qualified and experienced for the role, at the time of inspection she had not completed unit two of the Person Responsible Entry Programme (PREP). The PR explained that this was a genuine oversight on her behalf.
Areas for consideration
None.
Executive recommendations for Licence Committee
To comply with Standard 4.1.5 (Code of Practice 7th Edition) the PR should complete the PR Entry Programme. As the 8th Code of Practice comes into force on 1 October 2009 it is recommended that the PR complete the PREP for the 8th Code of Practice.
Evaluation
Some improvement required.
Areas not covered on this inspection
Risk Management.

2. Quality of service

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

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

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Live birth rates

Live birth rates[1]
In the time period from the 1 March 2007 to 7 July 2009 the centre's outcomes were in line with the national average.
Areas of firm compliance
The centre has an electronic quality management system in place. The quality manager also has clinical responsibilities but reported that she has sufficient time dedicated to this role. The centre was certified as ISO 9000:2001 compliant in June 2008. The centre holds an annual management review meeting each January setting out the key performance indicators for the forthcoming year. An action plan is drawn up and reviewed quarterly. This information is discussed at the monthly multi-disciplinary team meetings. Evidence of the annual meeting and action plan were made available to the inspectorate and was considered appropriate. Quality performance indicators have been established and evidence of monitoring clinical and laboratory practices was provided in the course of the inspection. Seven patient questionnaires were returned to the HFEA: three respondents made positive comments about the treatment they received. The centre also performs its own patient satisfaction survey. All patients undergoing intrauterine insemination (IUI) or in vitro fertilisation (IVF) treatment are given satisfaction questionnaires to complete. The forms are anonymous and collected in a box at the reception area. They are reviewed six monthly and routinely presented at the annual management review and the 6 monthly Medical Advisory Committee (MAC) meetings. Staff are encouraged to make suggestions at the weekly team meetings and at the annual management review.
Areas for improvement
None.
Areas for consideration
None.

Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
Document control.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

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

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Since the last inspection no major changes have been made to the premises. The areas seen during the visit appeared to be clean and well presented. The emergency trolley located within the three bedded recovery area was checked and found to be well maintained. It is checked on a daily basis and entries were seen to be made in an appropriate log. Counselling services are provided off site at the counsellor's own place of business. The counsellor confirmed that if patients wished to be seen within the centre a consulting room is made available. The counsellor explained that all fertility patients counselling notes are held in a locked filing cabinet separate from other counselling notes that he alone has access to. The PR confirmed that she will be visiting the counselling facilities in September 2009 to ensure that all counselling notes are held securely and confidentially and that the facilities are suitable. The laboratory staff confirmed that since the last inspection, no significant changes have been made to the equipment. The centre's current cryostorage facilities appeared to be adequate for the volume of work being conducted. The cryostore is fitted with a low level oxygen monitor. All dewars have low level nitrogen alarms and the centre has a procedure in place for responding to alarms. Logs of monitoring activities carried out in the laboratory are kept and these were seen by the inspection team. Procedures have been implemented to ensure the traceability of consumables that come into contact with gametes and embryos. Staff facilities including a changing area, toilet/shower and lockers along with a kitchen for staff use were considered appropriate by the inspectorate. The main administration/nursing office contains the current patient notes in locked filling cabinets. Notes for patients who have completed their treatment are archived and stored in locked filing cabinets in a separate room.

Areas for improvement
Air quality was monitored in August 2009 and the centre could provide evidence of the background air quality (Grade D). However the centre could not provide evidence of the grade of air quality in the areas where gametes and embryos are processed.
Areas for consideration
The counsellor sees patients and stores counselling notes at his place of business rather than at the centre.
Executive recommendations for Licence Committee
To comply with Licence Condition A.10.19 the PR should ensure that the processing of gametes and embryos while exposed to the environment must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross contamination between donations. To achieve this, such gametes and embryos must be processed in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP) Annex 1 and Directive 2003/94/EC. The effectiveness of these measures must be annotated and monitored. As the counsellor stores counselling notes and sees patients in his consulting rooms the PR should visit the premises and carry out a risk assessment to ensure: • All counselling notes are held securely and confidentially (Code of Practice, 7th Edition, A.10.31, S.7.2, G.10.31, G.7.2, G.7.4). • The facilities are provided in quite, comfortable, private and confidential surroundings (Code of Practice, 7th Edition, G.7.2, G.7.4 and S.6.3.5, G1.4.1).
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

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

- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
An audit was conducted on five sets of patient notes. All sets of notes were well maintained and contained the relevant consent forms. Discussions held with staff confirmed that the centre has appropriate procedures in place to ensure that proper account is taken of the welfare of the child when considering treatment. Discussions with the PR confirmed that they have a procedure for responding to patient requests for access to their medical records. There were no reported problems of late reporting from the Registry Department of the HFEA.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvements required.
Areas not covered on this inspection
Information for service users.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Clinical practice
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	3
Non NMC registered clinical staff	1
HPC registered scientists	2
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	3
Counsellors	1

Summary of laboratory audit
A summary of the findings of an audit of stored material was submitted prior to the inspection. No discrepancies were reported.
Summary of spot check of stored material
A spot check was not carried out as this was an interim inspection.
Areas of firm compliance
The three embryo transfer log provided evidence that no three embryo transfers had been conducted on women under the age of 40. There are documented procedures for procurement, packaging, distribution, recall and receipt of gametes and embryos that ensure: quality and safety of the gametes; risk of contamination is minimised; evaluation, assessment and safety of the provider and that procurement conforms with appropriate age limits for gamete providers. During the inspection evidence was provided to ensure that materials and equipment which comes into contact with gametes and embryos are traceable from procurement to disposal. The centre staff explained and demonstrated that their witnessing protocols ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process in order to prevent mismatches of gametes or embryos at any point of

the laboratory or treatment process. The counsellor is a member of the UK Council for Psychotherapy (UKCP) and has over twenty years experience of infertility counselling. There is no waiting list for counselling and appointments are made directly with the counsellor.
Areas for improvement
At present, no inter-laboratory reviews of practice are conducted. The PR explained that due to staff changes within the laboratory this has not as yet been set up. The PR stated that she is in the process of organising inter-laboratory reviews with two private centres in the area (centre 0208 and centre 0015). This was also noted at the time of the previous inspection.
Areas for consideration
None.
Executive recommendations for Licence Committee
The PR shall arrange for the centre to participate in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality assessment schemes) and by other external bodies. The results of these comparisons should be evaluated and documented and relevant findings be used to improve the service. (Code of Practice 7th Edition S.9.2.6).
Evaluation
Some improvement required.
Areas not covered on this inspection
Staff training and competency. Counselling audit.

Report compiled by:

Name: Paula Nolan

Designation: Inspector

Date: 6 August 2009

Appendix A: Centre staff interviewed

PR, Clinical Nurse Manager/Quality Manager, Independent Counsellor, Senior Embryologist/acting Lab Manager.

Appendix B: Licence history for previous 3 years

Licence Committee 17 December 2008
Approval given to renew centre's licence.

Licence Committee 2 May 2007
Approval given to vary the centres license in accordance with the requirements of the EU Tissue and Cells Directive.

Licence Committee 18 January 2007
Approval provided for the opening of the Agora centre.

Appendix C: Response of Person Responsible to the inspection report

Centre Number: 0254

Name of PR: Carole Gilling-Smith.

Date of Inspection: 5.8.09

Date of Response: 11.11.09

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

Signed……
…

Name: Carole Gilling-Smith

Date: 11.11.09

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

We felt that the report did not highlight the huge effort made on the part of the team and recognised by the inspectors at the time of their visit to achieve a Quality Management system which has been inspected to ISO 2000: 9001 standard. External assessors of the QM system have ranked this clinic as performing to one of the highest standards they have observed in the UK.

The inspection team commented very positively on all the feedback questionnaires they had received from patients attending in our centre. This is not highlighted as a positive comment in our report.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

The air quality was monitored throughout the lab and treatment room on 3rd August 2009. Unfortunately we did not receive the results until the 19th August 2009. A member of the Eastbourne DGH Quality Control and Pharmacy Department sampled air at 18 different locations. The results indicate that the lab air quality is better than Grade D. The Class II hoods were tested by Hunter Scientific and we were told that they were fully functioning and thus providing Grade A/B air. However, we agree this has not been tested formally. Therefore we have arranged to have these areas tested by Eastbourne DGH Quality Control and Pharmacy Department on the week of 16th November 2009. We can provide you with these results as soon as they are available. Full testing in the areas of

gamete/embryo processing and the background lab have been arranged to take place regularly henceforth.

The PR entry program unit 2 was not completed partly due to a misunderstanding of timescales. The HFEA had logged incorrectly the PREP as having been completed and had not chased the PR therefore for this to be done. It was the PR who herself flagged this up at the inspection. Due to the recent updating in the Act it has been agreed with the clinic's inspector that the PR will duly complete the new PREP by the end of November 2009.

The PR has made arrangements to visit the counsellor's premises and carry out a risk assessment.

The PR has taken steps to ensure inter laboratory comparisons will take place in 2010.

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

We plan to ensure that results are available on a regular basis to provide evidence of our air quality compliance.

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

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

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

Please return Appendix C of the report electronically to debra.bloor@hfea.gov.uk or in hard copy to:

Dr D Bloor (Head of Regulation)
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Executive Licensing Panel Meeting

16 December 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

The Agora Gynaecology and Fertility Centre (0254), Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Trish Davies, Director of Compliance	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Committee:

- papers for Licence Committee (32 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel noted that this centre is a private centre that treats both self funded and NHS patients, and provided 227 cycles of IVF/ICSI/FET and DI in 2008.

2. The Panel noted that the Person Responsible, Dr Carol Gilling-Smith, has been in post since 2007 but has not completed unit 2 of the PR Entry Programme, which is a requirement of standard 4.1.5 Code of Practice 7th Edition.

3. The Panel noted that at the time of the inspection the inspectorate had identified the following outstanding areas for improvement:
   - The PR to complete the Person Responsible Entry Programme
   - Monitoring Air Quality
   - Participating in inter-centre or inter-laboratory comparisons
   - Ensuring that the counsellor notes (storage) and premises are complaint with Code of Practice (7th Edition) guidance.

4. The Panel noted that the inspectorate had received additional information from the centre before this meeting, which pertained to evidence that the centre has now addressed the requirements on air quality and noted this information.

5. The Panel noted the inspectorate's recommendation that the centre's licence should continue with no additional conditions and endorsed the inspectorate's recommendations within the report and relevant timescales.

6. The Panel noted the Person Responsible's response to the inspection report and noted that the PR is taking positive steps to address the outstanding completion of the PR Entry Programme and to implement the inter laboratory comparisons.

7. The Panel noted that the PR has made the arrangements to visit the counsellor's premises and carry out a risk assessment. However, the Panel requests the inspectorate to follow up and check that this has been completed.

<u>The Panel's Decision</u>

8. The Panel agreed that the licence should continue with no additional conditions and endorsed the inspectorate's recommendations. The Panel considered that the Person Responsible should complete the PR Entry Programme by 31 January 2010.

Signed Peter Thompson ..... Date 4 January 2010.
Peter Thompson (Chair)