Interim Inspection Report

Bristol Centre for Reproductive Medicine
0295

Date of Inspection: 23rd July 2008
Date of Licence Committee: 13th October 2008

Centre Details

Person Responsible	Peter Wardle
Nominal Licensee	Gillian Ryan
Centre name	Bristol Centre for Reproductive Medicine
Centre number	0295
Centre address	North Bristol NHS Trust Southmead Hospital Westbury on Trym, Bristol, BS10 5NB
Type of inspection	Interim
Inspectors	Ellie Suthers, Vicki Lamb, Parvez Qureshi and Stacey Kennedy (Observer)
Fee paid	Paid
Licence expiry date	18th December 2010
NHS/Private/Both	NHS and self funded

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About the Inspection:

This inspection visit was carried out on 23rd July 2008 and lasted for 6.5 hours. The report covers the pre-inspection analysis, the visit and information received since the last inspection.

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

Bristol Centre for Reproductive Medicine (0295) is an amalgamation of Southmead Fertility Centre 0032 (NHS) and the Centre of Reproductive Medicine, University of Bristol 024 (private) in January of 2008. The new centre is housed in a new purpose built facility on the Southmead Hospital campus of North Bristol NHS Trust. Equipment, service user health records and stored material have been transferred onto the new site. An amalgamation of staff of the two centres has taken place with a new organisational structure in place. New premises preliminary and additional inspections were carried out on the 29th August 2007 and 3rd of December 2007 respectively and the Authority's executive recommended that licence treatment could commence at the centre.

The Person Responsible (PR), Mr Peter Wardle who is a Consultant in Obstetrics and Gynaecology completed the Person Responsible Entry Programme in August 2007 and is suitably qualified. Mr Wardle was previously the PR for Southmead Fertility Centre.
Ms Gillian Ryan is the Nominal Licence (NL) and also the Assistant General Manager (AGM) for the centre.

Activities of the Centre[1] for the time period from 1st January 2008 – 1st July 2008

In vitro fertilisation (IVF)	180
Intracytoplasmic sperm injection (ICSI)	233
Frozen embryo transfer (FET)	41
Intra uterine insemination (IUI)	
Gamete intrafallopian transfer (GIFT)	
Research	
Storage gametes/embryos	yes

Summary for Licence Committee

This interim inspection report follows a number of new premises inspections and reports. The focus of the inspection, after discussion with the staff at the centre, was to evaluate compliance with licence requirements as the new centre adjusts to the new systems and processes, organisational structure and increasing activity.

This is the first inspection following the amalgamation of two centres into one. Premises and facilities were approved by the licence committee on 28th January 2008 and remain suitable for licensed activity.

The new centre appears managerially well organised with clearly demonstrated areas of responsibility and lines of accountability. The senior management team demonstrated an

[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.

understanding of the difficulties and possible associated problems with merging the centres and have been proactive in managing the transition. Team building and strategic management training have been undertaken. Some of the systems and processes of the two centres were running in parallel at the time of inspection. Gradually these will be brought together in a managed way. Evidence was seen of appropriate clinical and laboratory practices delivered by staff that are appropriately qualified and take part in ongoing continued professional development.

It is anticipated that activity will increase to 1000 cycles by the end of 2008. The PR reassured the inspectorate that there are sufficient space and resources in place to achieve this.

Areas for improvement:

- Continued development and completion of third party agreements;

Following this inspection the inspection team recommends the continuation of the Bristol Centre for Reproductive Medicines' licence with no additional conditions.

Evaluations from the inspection

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

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

Breach	Action required	Time scale
The NL informed the inspectorate that approximately 70% third party agreements have been confirmed with signed contracts and the remaining 30% are awaiting response from the individual suppliers. *(CoP A.5.1)*	The Centre should continue efforts to establish written agreements with all Third Parties for external activities which influence the quality and safety of gametes and embryos procured or processed.	To be reviewed at the next inspection

Non-Compliance

Area for improvement	Action required	Time scale
None identified at this inspection		

Recommendations

Area for improvement	Action required	Time scale
Non identified at this inspection		

Changes/ improvements since last inspection

Recommendations	Action Taken
No recommendations were made at the time of the last premises inspection.	

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1.Organisation

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

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

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

Areas of firm compliance

Leadership and management:
The Person Responsible (PR) is Mr Peter Wardle who is a Consultant in Obstetrics and Gynaecology, has completed the Person Responsible Entry Programme in August 2007 and is suitably qualified. Mr Wardle was previously the PR for Southmead Fertility Centre. *(CoP: S.4.1.5: S.4.1.4)*
Ms Gillian Ryan is the Nominal Licence (NL) and also the Assistant General Manager (AGM) and Quality Manager for the centre.
There are clear organisational accountability and reporting relationships that were demonstrated via four organisational charts (Managerial/Non Clinical/Scientific/Nursing) and during interviews between the inspection team and centre staff. *(CoP: S.4.2.6)*.
The senior management team has recognised potential challenges in bringing two teams with different working practices together in one structure and have undertaken team building and organisational development training in order to make the transition smooth.

Organisation of the centre:
During the inspection the centre appeared to be operationally well organised. All pre inspection material had been submitted to the HFEA inspectorate complete and on time. All members of staff who were present for the inspection provided all the information requested both written and verbal. Each member of staff approached appeared to the inspectors to know about the inspection process and provided information and comment when asked.

The centre is open 7 days per week; on weekdays between 8am and 5pm for full activity. At weekends staff provide an on-call service for embryo transfer, scanning and intra-uterine insemination.

Resource Management:
The PR informed the inspectorate that the employment contracts of all members of staff have now been transferred to the North Bristol NHS Trust and that there are sufficient staff and resources available for the activity in the centre. *(CoP S.6.2.1)* It is planned to increase activity to from 800 to 1000 cycles annually over the coming year.

Incident Management:
The inspectors observed a documented procedure for the identification, investigation, control and recording of adverse incidents. The documentation was seen to be up to date and complete. A North Bristol NHS Trust policy is followed. Any incidents are reported on an adverse incident management system (AIMS) form via the relevant line manager to the clinical governance committee for discussion.
Staff demonstrated their knowledge and understanding of the incident reporting procedures during interviews with inspectors and in centre meeting minutes. It is the responsibility of the PR to report to the HFEA where required. Evidence of compliance with the requirements for reporting to the HFEA was observed in the course of the inspection *(CoP A.4 : S.9.4.1)*

The procedure for the receipt, management and dissemination of HFEA alerts is managed via the PR and quality manager who assesses each alert and the possible impact on the centres practises. Documented evidence of this was observed in the incident management log.

Meetings/dissemination of information:
Agendas and minutes were examined by the inspectorate of: weekly audit meetings, weekly senior management meetings, monthly multidisciplinary meetings, multi individual discipline meetings and bi monthly clinical governance meetings. The minutes described staff input and discussions. Minutes are circulated amongst staff and are available from a centrally stored file. *(CoP S.6.2.13)*

Clinical Governance:
The centre holds bi monthly clinical governance meeting to which all members of staff are invited. This provides a forum for clinical discussion, agreeing of management and clinical changes or decisions and for training and staff input. Evidence of standing agenda items such as HFEA alerts, adverse incidents, complaints were noted by the inspectorate. *(CoP S.6.2.13 S.9.4.3)*

Contingency arrangements:
The centre has draft reciprocal contingency arrangement in progress with the Bath Assisted Conception Unit. *(CoP S.6.3.4 (b))*

Payment of treatment fees:
The HFEA Finance department confirmed that all fees are paid as invoiced and within prescribed timeframes
(CoP A.16.3)

Areas for improvement
Third party agreements: The centre manages all its own third party agreements with individual suppliers of consumables and equipment. The NL informed the inspectorate that approximately 70% have been confirmed with signed contracts and the remaining 30% are awaiting response from the individual suppliers. *(CoP A.5.1 and S.4.2.10.)*
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
The centre should continue to work towards establishing all third party agreements by the time of the next inspection.
Evaluation
Some improvement required
Areas not covered on this inspection
None

2. Quality of service

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

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

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

Live birth rates[1]
This centre only commenced licensed activities in January 2008. Pregnancies have been achieved since the opening of the new centre but too few treatment cycles have been reported to allow statistical evaluation.
Areas of firm compliance
Quality Management System: The quality management system has been completely reviewed and updated prior to and during the merger of the two centres. Both centre 0024 and 0032 had achieved ISO 9000: 2001 accreditation prior to the merger. An external advisor (International Organisation for Standardisation (ISO) consultant) undertook a whole systems audit of centre 0295 on behalf of the PR. ISO and quality management system training was provided to all staff during a clinical governance training day in April 2008. Evidence of staff collaboration in the development of the quality management system was observed in the course of the inspection. Quality objectives have been established. *(CoP S.4.2.4)* The quality manual appeared compliant with the requirements of the 7th Code of Practice. Six members of staff from all disciplines have been trained in audit techniques and a rolling programme of audits was observed including: results, pregnancy, and fertilisation rates, ICSI practitioners, embryo transfers, complaints, significant incidents and others. *(CoP S.4.2.9,, S.6.2.11. S.9.1.2)* **Service user feedback including suggestions and complaints:** The centre has a written procedure in place for the acknowledgment and investigation of complaints as per the North Bristol NHS Trust policy. It was observed that this policy contains timescales for response, arrangements for investigation and the role of the centres designated complaints officer. The centre's complaints log was seen to contain detailed records of complaints, resolution and outcomes. (*CoP S.9.2.2).*

The inspectorate observed a protocol on how service user's views are obtained via two questionnaires. (70% return rate) Results are presented at monthly team meetings and outcomes analysed. The inspectorate observed service improvement and changes as a result of suggestions. A service user involvement group provided input into the planning, decor, literature and artwork in the new facility. A service user chat room, moderated by three service users is available on the centres website.

Two service users were interviewed during the inspection, both were content with the new facilities, appointments were normally on time and they were able to contact the centre and staff easily. Both commented that the information provided prior to consent to treatment was easy to understand and that staff were helpful during consultations.

Document control:
Consistent document control was observed, including a document control policy, to be in place for all standard operating procedures (SOP), clinical and management policies reviewed in the course of the inspection. *(CoP S.5.2.5)*

Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
No executive recommendations for Licence Committee
Evaluation
No improvements required
Areas not covered on this inspection
Live birth rates

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
Description of facilities: The centre is located on two floors in a designated, purpose built building on the Southmead hospital campus. The ground floor houses all the service user areas, clinical and treatment rooms, laboratories, operating rooms, recovery bays and storage areas. The first floor provides an open plan area for administration and staff areas. The waiting area has a modern feel with both natural and artificial lighting. The frosted tempered glass and wooded reception counter has been designed in a curve for flow of traffic and has provision for patients with disabilities. It was also observed that there are normally two members of staff at the desk. The seating arrangements are adequate and patient confidentiality is well maintained. The HFEA Licence, centre's complaints procedure and its ISO certificate are displayed on the notice board in this area. There are ten multipurpose consulting/clinical rooms located on the ground floor used by medical and nursing staff. The counselling room is purposely located at the main entrance to the facility so as to maintain privacy and confidentiality of patients who require this service. There are three male production rooms located on the ground floor in a secure private area away from the main waiting area and patient thoroughfare. One of the rooms has been designed for specifically for use by oncology or disabled patients. There are well signed individually designated hatches for treatment and diagnostic samples with a bell for collection. There are three theatre units which have been designed specifically for the procedures performed at the centre. Each unit is linked with the laboratory for collection and transfer of gametes. There is also a six bed recovery area which is monitored by theatre nurses. The laboratory suite and administration office are based on the ground floor and are linked via hatches to the theatres. The main open plan office facilities are located on the second level of the building which also has lift access.

Security is maintained in the centre as all areas are accessed either via a key code entry lock or with a swipe card. Service user access to the centre is via a designated main entrance which is on view from the main reception at all times.

Secure storage facilities for personal belongings are provided for staff along with facilities for refreshment and work breaks *(CoP S.6.3.4)*

All these areas were inspected for licence premises compliance and approved by the licence committee on 28th January 2008. All clinical, laboratory and counselling facilities were seen to be suitable for licensable activities and maintained to suit their intended purpose *(CoP S.6.3.3: S.6.3.6: S.6.3.7)*

Air Quality:
At the time of inspection it was observed that air quality is monitored quarterly and results documented. The most recent results demonstrated air quality in compliance with requirements. *(CoP A.10.19)*

Management of equipment:
A maintenance log provided information on the servicing, cleaning and disinfection of critical equipment. Documentation was also observed of the management and re commissioning of relocated equipment (laboratory and clinical) in accordance with manufacturer's instructions (*CoP S.6.4.2)*
Contingency arrangements are in place in the case of power failure: the laboratory and operating theatre suites have uninterrupted power supply (UPS) facilities as have the main embryo culture incubators and the embryo freezing equipment.

Storage facilities for gametes and embryos:
All storage dewars are locked with monitoring devices in place which are attached to an auto dialler to contact an on call member of staff in the event of failure *(CoP S.6.3.7)*. It was noted during inspection that the laboratory is moving from scheduled monitoring towards continuous monitoring of critical equipment. *(CoP S.6.4.2).* The cryo store was observed to be of an appropriate size and secured by a key pad entry lock. *(CoP S.6.3.8)*

Storage of records:
All locations where health records are held are locked and away from the main waiting area. A lockable storage system is located in the main open plan administration area on the second floor which is not accessible by service users or visitors without permission *(CoP S.7.2.1 & S.6.5.1)*

Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration

Executive recommendations for Licence Committee
No recommendations
Evaluation
No improvements required
Areas not covered on this inspection
None

4. Information

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

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

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance

Information for service users:
The centre provided all updated service user information, leaflets and literature at the beginning of 2008. A small selection was reviewed prior to inspection: each of 6 pieces of information reviewed was found to contain appropriate information. *(CoP S.7.4.1)*

Consent:
Evidence was observed of service user literature providing written information about the clinical, scientific and legal implications of treatment. During discussions staff confirmed that service users are given information and time to consider their treatment. Service users interviewed during the inspection confirmed that they were content with the information provided both in literature and in discussion with staff.
All service users are referred by their GP or consultant and complete a patient identification form which also contains photographs and signatures. These are checked at each attendance and when consents to treatment are taken. *(CoP S.7.5.2)*

Relevant and appropriately signed consent forms compatible with the treatments provided were observed in eight sets of service user records

Welfare of child:
The centre has welfare of the child policy that contains relevant information and guidance for staff. During interview staff confirmed that any concerns over the welfare of any child could be raised at a number of stages before or during treatment. Discussions with a referring GP, clinical governance meetings, and interviews with the service users are described in the policy. *(CoP S.7.1.2)*
It was observed during a service user health records audit of (8 sets of records) that all had signed welfare of the child declarations.

Confidentiality and access to health records:
Centre staff are trained on the requirements for confidentiality as part of their induction and are required to sign a confidentiality declaration. All staff that access service user information are named on the HFEA Licence.

Provision of information to the HFEA register:
The HFEA registry confirms that there are no issues relating to the provision of information.

Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
No recommendations from the Licence Committee
Evaluation
No areas for improvement
Areas not covered on this inspection
None

5. Clinical, laboratory and counselling practice

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

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - 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
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	7 doctors = 5.2 wte + 7 consultant anaesthetists = 1.2 wte (sessional)
NMC registered nurses	13.5 wte
HPC registered scientists	7 wte
Scientists working towards registration	5 wte
Support staff (receptionists, record managers, quality and risk managers etc)	18 This includes HCA's
Counsellors	1 wte

Summary of laboratory audit
The centre commenced licensable activities in January 2008. There is an ongoing audit of all material following the transfer from other sites. The outcome of the audit will be reported to the HFEA when complete. Once complete the centres from where the material was transferred will be formally closed.
Summary of spot check of stored material
On discussion with the scientific director and inspector it was agreed that as an audit is ongoing following the move of stored material no spot check of stored material would be carried out at this inspection.
Areas of firm compliance
Staff training and competency: During the inspection clinical and scientific staff provided evidence of continued professional

development in training logs. The training log for a member of the nursing team provided signed evidence of scanning competency checks and certificates confirming training and education in relevant subjects. During interviews with staff it was confirmed that staff attend and participate in national and international conferences e.g. European Society for Human Reproduction & Embryology (ESHRE), The Association of Clinical Embryologists (ACE). And the Royal College of Nursing congress (RCN)
A number of nurses have completed or are undergoing British Fertility Society (BSF) training programmes. Appropriately trained senior nurses carry out embryo transfers and IUI's each taking part in regular audits of technique and outcomes. The quality manager has undergone training and supervision in the development and maintenance of the quality management system and the senior management team have undergone leadership management training. ICSI practitioners audit compliance with protocols and outcome. Laboratory staff participate in the National External Quality Assessment Service (NEQAS) for semen analysis.
From the evidence and discussions on the day of inspection staff are appropriately registered and possess the appropriate qualifications and/or experience set out in relevant HFEA and professional guidance. *(CoP S.6.2.2)*
All staff attends corporate and local induction programmes and undergo annual appraisal from which personal development plans are generated.

Screening of donors:
Donors are recruited through local publicity and patient appeals. Service users are also able to participate in a known donation programme following consultation and counselling. It was observed in protocols and service user health records that the required donor screening from professional guidelines are carried out and that there is comprehensive service user information available.
The sperm donor coordinator demonstrated evidence of training and competence in gamete procurement on discussion with the inspector and A.C.E certification in her training log book*(CoP S.7.6.7)*

Witnessing:
It was observed that the centre has witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory processes. Discussion with staff and a review of patient records confirmed that witnessing is carried out in accordance with HFEA guidance *(CoP S.7.8.15)*

Counselling practice:
A detailed counselling audit was provided prior to the inspection detailing referrals and attendances for therapeutic and egg and sperm donation counselling. A poster displayed in the main waiting area advertises the service and during discussion with staff the inspectorate were informed that staff offer counselling as a matter of routine prior to and during treatment. *(CoP S.7.6.2)*

The centre has two counsellors providing services for either self funded or NHS service users. (the counsellors have transferred from centre 024 and 032 and maintain the separation between self funding and NHS service users) Appointments are available each day including evenings, Saturday mornings and telephone counselling appointments. Additionally there is an external supervisor who provides support and guidance.

Counselling is free to both self funding and NHS patients with sessions also offered for

genetic counselling, donor counselling and relationship issues. An interpreter is available through an interpreting service which is pre booked where required.

It was noted that the Counsellor interviewed during the inspection is a BICA Training Group member and demonstrated relevant qualifications, continuing professional development, registration and supervision. *(CoP G.1.4.2)*
It was observed that service user counselling records are stored securely. *(CoP G.7.4.1)*

It was observed that records are kept of the materials used in the processing and storage of gametes. Lot numbers and item reference numbers of were seen to be centrally logged. Batch numbers are allocated on delivery to the unit. The dates of first and last use of these materials are recorded centrally. (CoP S.7.3.2)

Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
No recommendations for the Licence Committee
Evaluation
No improvements required
Areas not covered on this inspection
Procurement, distribution and receipt of gametes and embryos; Traceability and coding Coding/ identification of samples were covered at the last inspection.

Report compiled by:

Name	Ellie Suthers
Designation	Inspector
Date	18th August 2008

Appendix A: Centre staff interviewed

Mr Peter Wardle – PR
6 members of staff
2 service users

Appendix B: Licence history for previous 3 years

2007
Initial three year licence issued on the 19th of December 2007 with no conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number	0295
Name of PR	Peter Wardle
Date of Inspection	23rd July 2008
Date of Response	15th September 2008

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

Signed……

Name	Peter Wardle
Date	15th September 2008

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.

Six typing and factual inaccuracies were identified by the centre and have now been corrected in the main body of the 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.

We are delighted to have received such a favourable inspection report following the merger of our two well established IVF units in Bristol, welcoming particularly the inspection team comments relating to the robustness of our procedures.

We are also pleased to report to the inspection committee that awe are continuing to achieve the success rates we have enjoyed in recent years and, furthermore, would like to add that early indications are that we are also achieving increased success in relation to frozen embryo transfer pregnancy rates. We hope to increase these rates further still following the introduction of a new embryo vitrification programme in the New Year.

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

We shall be reviewing third party agreements on a monthly basis to ensure all agreements have been returned by our suppliers.

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

Licence Committee Meeting

15 October 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Bristol Centre for Reproductive Medicine (0295)
Interim inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Chris O'Toole, Head of Research Regulation
Emily Jackson, Lay Member	Claudia Lally, Committee Secretary
Richard Harries, Lay Member	
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Providing Legal Advice to the Committee: Mary Timms, Field Fisher Waterhouse Solicitors

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 (25 pages)
- no tabled papers.

1. The papers for this item were presented by Chris O'Toole, Head of Research Regulation. Dr O'Toole informed the committee that this was the first inspection following the amalgamation of two centres into one. She reported that the inspection found that the new centre appeared to be well managed, the premises were suitable and clinical and laboratory practices were considered appropriate. The only area for improvement identified at the inspection was the requirement for the centre to complete its third party agreements.

2. Dr O'Toole informed the Committee that since the time of the inspection the centre has been working hard to complete its third party agreements and to date has completed 70%.

3. The Committee noted the inspection report and the progress that the centre is making with respect to the completion of third party agreements. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)