Interim Inspection Report

Bristol Centre for Reproductive Medicine
0295

Date of Inspection: 22 July 2009
Date of Executive Licensing Panel: 14 October 2009

Centre Details

Person Responsible	Mr. Peter Wardle
Nominal Licensee	Miss Sarah Hughes
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
Inspector(s)	Jenny McLaughlin
	Ellie Suthers
	Jason Kasraie (external advisor)
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 22 July 09 and lasted for 5 hours.

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 makes 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 (BCRM) is an amalgamation of Southmead Fertility Service and the Centre of Reproductive Medicine, University of Bristol. It is located in a new purpose-designed building on the Southmead hospital campus of North Bristol NHS. It opened in January 2008 and is an NHS service which can be accessed by patients on a self funding basis.

Equipment, service user health records and stored material have been transferred to the new site. An amalgamation of staff of the two centres has taken place and a new organisational structure is in place. An interim inspection took place in July 2008 and after consideration of the inspection report, a Licence Committee approved the continuation of the centre's licence with no additional conditions. This centre's licence was first issued on 19 December 2007 and expires on 18 December 2010.

The centre provided approximately 1800 licensed treatment cycles between June 2008 and May 2009. The centre is open Mon-Fri 8am-5pm and provides an on-call service on Saturdays and Sundays for embryo transfers, scans and IUIs.

The Person Responsible (PR), Mr. Peter Wardle is a Consultant in Obstetrics and Gynaecology. Mr. Wardle was previously the PR for Southmead Fertility Centre. On 22 June 2009, Licence Committee approved an application to vary this centre's licence to recognize Miss Sarah Hughes as the new Nominal Licensee (NL). Miss Hughes is also the assistant general manager for fertility services and quality manager for the centre.

Activities of the Centre[1] for the time period from 01 June 08 – 31 May 09

In vitro fertilisation (IVF)	471 cycles
Intracytoplasmic sperm injection (ICSI)	615 cycles
Frozen embryo transfer (FET)	18
Donor insemination (DI)	66 cycles
Gamete intrafallopian transfer (GIFT)	none
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

The purpose of this interim inspection was to evaluate the centre's progress since the amalgamation of the two centres last year. The previous interim inspection took place in July 2008 and found this centre to be well-managed and largely compliant in all areas. The focus of this inspection was on the following areas:

1) follow-up on the breach identified at the last inspection

[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) areas that were not covered at the last inspection (procurement, distribution and receipt of gametes and embryos)
3) incidents since the last inspection
4) quality management system
5) audit of transferred stored material

Suitability of the PR
The PR is suitably qualified and in considering overall compliance of the Bristol Centre for Reproductive Medicine, the PR is considered to have discharged his duties satisfactorily under S.17 of the HFE Act.

Suitable premises and equipment
Premises and equipment were unchanged since the last inspection and at the time of this inspection were observed to be suitable for the activities for which the centre is licensed.

Suitable practices
At the time of this inspection, practices observed were considered suitable.

The new centre appears managerially well organised with clearly demonstrated areas of responsibility and lines of accountability. The senior management team demonstrated an understanding of the possible challenges associated with merging the centres and have been proactive in managing the transition. Staff appeared to be very conscious of the HFEA and demonstrated an awareness of regulatory requirements.

Areas of improvement
- payment of HFEA invoices within required timeframe
- reporting cases of severe OHSS as adverse incidents

The inspectorate considers that there is sufficient information on which to recommend the continuation of the Bristol Centre for Reproductive Medicine's licence.

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
At the time of the inspection, the centre was taking an average of 51 days to pay their HFEA invoices. This is considered a breach of Standard Licence Condition A.13.3.	The PR should review payment processes to ensure the payment of HFEA fees within 28 days of the date of the notice.	To be assessed at the next inspection.
One case of severe OHSS was not reported to the HFEA. Severe cases of OHSS are considered to meet the definition of an adverse reaction and must be reported to the HFEA in accordance with Standard Licence Condition A.4.5.	The PR should ensure that cases of severe OHSS are reported to the HFEA within the timeframes specified in S.9.4.2 of the Code of practice.	To be assessed at the next inspection.

Non-Compliance

None identified at this inspection.

Recommendations

None identified at this inspection.

Changes/ improvements since last inspection

Recommendations	Action Taken
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.	The PR reported that all third party agreements have been established in compliance with standard licence condition A.5.1. A list of all agreements was provided at inspection and a sample examined appeared compliant with guidelines.

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 PR has completed the HFEA PR training programme and is considered appropriately qualified and experienced for the role. (CoP S.4.1.5; S.4.1.4) An organisational chart was supplied pre-inspection that indicates lines of responsibility. (CoP S.4.2.5) Minutes from the centre's Annual Management Review demonstrates a commitment to the maintenance of the Quality Management System and the continual improvement of its effectiveness (CoP S.4.2.1) **Organisation of the centre** At inspection the centre was observed to have an organisational structure which facilitates the creation of an environment in which all medical, nursing, scientific, counselling and other staff are fully involved. (CoP S.4.1.3) Operational procedures reviewed pre-inspection were found to be appropriate to the activities for which the centre is licensed. (CoP S.4.1.1) **Resource management** The PR informed the inspectorate that there are sufficient staff and resources available for the activity of the centre. (CoP S.6.2.1) **Clinical governance** The centre holds a bi-monthly clinical governance meeting to which all members of staff are invited. This meeting provides a forum for clinical discussion, agreeing of management and clinical changes or decisions and for training and staff input. (CoP S.9.4.3). The centre has a written procedure in place for the acknowledgment and investigation of complaints as per the North Bristol NHS Trust policy. The centre's complaints log was observed to contain detailed records of complaints, resolution and outcomes. (S.9.2.2) Complaints information was clearly displayed in the patient waiting area.

Risk management
The centre provided documented evidence of risk assessments for both laboratory and clinical procedures that had been conducted since the last inspection. (CoP S.7.8.10, S.9.4.3) Risk assessments were also observed to have been undertaken in response to adverse incidents.

Incident management
The centre's incident management processes were observed and discussed in detail. The PR supplied a comprehensive log of incidents reported internally at the centre. Meeting minutes confirmed a proactive, team approach to the prevention and analysis of incidents. The centre's procedures require that all incidents, root cause analyses, and corrective actions are documented and discussed at management meetings. (CoP S.9.4.2) The centre's procedures also ensure that adverse incidents are reported to the HFEA within the timeframes specified in CoP S.9.4.2.

Contingency arrangements
The centre has a reciprocal contingency arrangement with the Bath Assisted Conception Unit. (CoP S.6.3.4 (b))

Establishment of third party agreements
The PR reported that all third party agreements have been established in compliance with standard licence condition A.5.1. A list of all agreements was provided at inspection and a sample examined appeared compliant with guidelines.

Meetings/dissemination of information
Discussion with staff confirmed that the centre holds monthly team meetings for all staff, and monthly team meetings for individual disciplines. (CoP S.6.2.13) All new or revised procedures are disseminated to all staff by email.

Areas for improvement

Incident Management
The PR was not aware that severe cases of OHSS resulting in hospitalisation are considered to meet the HFEA's definition of adverse reaction. (CoP S.3.1.26) One severe case of OHSS had been documented in the centre's incident log since the last inspection but was not reported to the HFEA as an adverse reaction. (CoP A.4.5). The PR agreed to report any future severe cases of OHSS to the HFEA.

N.B. It should be noted that in the 8th Edition of the Code of Practice, the definition of "adverse incident" is clearly defined to include OHSS cases graded as severe or critical and requiring hospitalisation.

Payment of licence/treatment fees
The centre is taking an average of 51 days to pay their invoices. The NL explained that the centre's finance policy is to pay invoices on/around 31st of every month and should invoices come in too late for this, they are paid at the end of the following month. The centre has committed to revise their policy in order to ensure that invoices are paid within the 28 day timeframe specified in licence condition A.13.3.

Areas for consideration

No areas for consideration.
Executive recommendations for Licence Committee
The PR should ensure that severe cases of OHSS are reported to the HFEA as adverse incidents and that centre staff are aware of this requirement. Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of the identification of the adverse incident and submit an adverse incident report form within 24 working hours in compliance with S.9.4.2. The PR should ensure that HFEA invoices are paid within 28 days in compliance with standard licence condition A.13.3.
Evaluation
Some improvement required.
Areas not covered on this inspection
Alert 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
- Document control
- Live birth rates

Live birth rates[1]
For the data reported for the time period from Jan 01, 2008 to June 1, 2009 live birth outcomes appear to be in line with national averages.
Areas of firm compliance
Quality management system The quality management system was completely updated following the merger of the two centres. Standard operating procedures were observed to be relevant to key activities and processes. (CoP S.5.2.2(a)) The centre underwent a whole systems audit and received ISO 9001:2000 re-certification in February 2009. A new quality manager has been in post since April 2009 and showed evidence at inspection of appropriate quality management experience. (CoP S.4.2.7) **Quality policy** The centre's quality policy, signed and dated, was observed to be posted in the centres' reception/waiting area. (CoP S.4.2.3) **Quality manual** A quality manual was observed to be compliant with the requirements of CoP S.5.2.3/4. The quality manual establishes the centre's documented quality objectives and plans to achieve and maintain these objectives (CoP S.4.2.4) **Document control** An effective electronic document management system was observed to be in place. This system ensures that the centre's documents are version controlled, regularly reviewed, revised as required, dated and approved promptly by authorised personnel. (CoP S.5.2.5). **Feedback** All patients are provided with up to 2 questionnaires; one for overall service and another for patients who have undergone a theatre procedure. All feedback forms are read by the senior team and a summary is provided at the monthly team meetings. (CoP S.9.2.1) **Quality management review/evaluation**

A quality management review takes place once a year. Minutes from the most recent annual management review meeting showed evidence that a quality management review had been undertaken.
Areas for improvement
No areas for improvement.
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
The executive has no recommendations for Licence Committee with regard to quality of service.
Evaluation
No improvements required.
Areas not covered on this inspection
None.

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

Premises

The centre was observed to have premises and facilities suitable for the activities for which it is licensed. (CoP S.6.3.2) A copy of the centre's Certificate of Licence was found to be clearly displayed in the patient waiting room. (Standard Licence Condition A.13.4) The centre appeared to be spacious, well-organised and clean. 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. The PR described the centre's procedure for lone workers, which uses security services provided by the Trust. (CoP S.6.3.2).

Clinical facilities

The ten multipurpose consulting/clinical rooms located on the ground floor are used by medical and nursing staff and appeared to provide for the comfort and privacy of patients. There are three sperm 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 specifically for use by disabled patients. (CoP S.6.3.4) 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.

Counselling facilities

The counselling room is located at the main entrance to the facility so as to maintain privacy and confidentiality of patients who require this service. The room appeared spacious, private and comfortable. (CoP S.6.3.5)

Laboratory facilities

Laboratory premises and equipment were observed to be of high standard and well designed and maintained for their intended purpose. Evidence of ISO accreditation and maintenance logs were observed at inspection. Staff reported that the unit is suitably equipped. (CoP S.6.3.6)

Management of equipment and facilities
At inspection, it was observed that CE marked consumables are used where possible. (CoP S.6.4.1) Documented evidence that new equipment is tested and validated before use was observed at inspection. (CoP S.6.4.2)

Storage facilities for gametes and embryos
The storage facilities for gametes and embryos were observed to be appropriate for the volume and activities conducted. The dewar store is protected by keypad lock and can only be accessed by lab staff and senior management. Each dewar was observed to be individually locked and monitored. (CoP S.6.3.8) Separate dewars are used for storing quarantined gametes and embryos. (CoP S.6.3.7)

Air quality
Air quality monitoring in all laboratory areas is performed on a quarterly basis through the use of particle counts and microbiological plating. Evidence of thorough air quality monitoring was observed on inspection and results were seen to meet or exceed requirements in all areas. Results of the most recent test were observed to be Grade B for background and Grade A in the area where gametes and embryos are processed. (Standard Licence Condition A.10.19)

Staff facilities
The first floor of the centre was observed to contain spacious staff facilities including toilet accommodation, a rest area with basic kitchen facilities and a supply of drinking water. The staff facilities in the laboratory area appeared to comply with requirements. (CoP S.6.3.10)

Storage of records
All locations where service user health records are held are locked and away from the main waiting area. A lockable storage system is located in the main administration area on the first floor which is not accessible by service users or visitors. (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
The executive has no recommendations for Licence Committee with regard to premises and equipment.
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 During the tour of the centre it was noted that appropriate HFEA and centre specific information was clearly displayed in patient areas. This included information regarding complaints, counselling services, and fertility support services. All patients receive a Key Services Guide before their first consultation and a patient information booklet for donor or IVF/ICSI treatment. (CoP S.7.4.1) **Provision of information to the HFEA register** The HFEA registry confirmed that information is reported in a timely and accurate manner. (CoP S.4.2.12)
Areas for improvement
No areas for improvement.
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
The executive has no recommendations for Licence Committee with regard to information.
Evaluation
No improvements required.
Areas not covered on this inspection
Consent Welfare of the child Access to health records

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	4.28
NMC registered nurses	16.1
Non NMC registered clinical staff	2
HPC registered scientists	2.8
Scientists working towards registration	10.4
Support staff (receptionists, record managers, quality and risk managers etc)	18.26
Counsellors	1 + additional as required

Summary of laboratory audit
The centre showed evidence of progress with their ongoing audit of all stored material transferred from centre 0032 in May 2008 as part of the merger. The centre assured the inspection team that the results of the audit will be reported to HFEA upon completion.
Summary of spot check of stored material
A physical spot check of stored material was not performed by the HFEA in light of the PR's serious concerns regarding maintaining the integrity of the stored samples.
Areas of firm compliance
Screening of donors Screening procedures were discussed with staff and were found to be in compliance with guidelines. (CoP S.7.8.12). Three sets of patient notes were inspected and screening was found to be compliant with Standard Licence Condition A.7.2 and in compliance with professional body guidelines. **Procurement, distribution and receipt of gametes and embryos** Records of donor registration were observed at inspection to include donor identification,

purpose of donation, medical history, clinical and laboratory assessment data, and donor consent. (CoP S.7.7.4)

The centre's protocol for transportation of samples was reviewed for compliance with HFEA Alert 21: Transport hazards of gametes/embryos nationally and internationally. The centre's protocol was missing two steps but this was corrected in the course of the inspection on identification of the omission.

Witnessing
Three sets of patient notes were audited and found to be compliant with requirements related to witnessing. (CoP S.7.8.15 and G.13.1.1)

Areas for improvement
No areas for improvement.
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
The executive has no recommendations for Licence Committee with regard to clinical, laboratory and counselling practice.
Evaluation
No improvements required.
Areas not covered on this inspection
Counselling practice Three embryo transfer Staff training and competency

Report compiled by:

Name…….Jenny McLaughlin……

Designation…….Inspector…….

Date……28 July 2009……

Appendix A: Centre staff interviewed

PR, NL/Quality Manager, Head of Embryology & Andrology, Clinical Nurse Manager

Appendix B: Licence history for previous 3 years

Licence	Status	Type	Active From	Expiry Date
L0295/1/c	Change in NL	Treatment with storage	07/07/2009	18/12/2010
L0295/1/b	Change in NL	Treatment with Storage	15/10/2008	18/12/2010
L0295/1/a	Initial licence	Treatment with Storage	19/12/2007	18/12/2010

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0295

Name of PR Mr Peter Wardle

Date of Inspection 22nd July 2009

Date of Response 28th September 2009

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

Signed……

Name Peter Wardle

Date 28th September 2009

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.

Four 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.

On page 9 of the report, under 'Incident Management' and on page 10, under 'Executive recommendations for Licence Committee', I believe our discussions at the inspection have been mis-reported. As PR, I have always been aware that severe cases of OHSS should be reported as adverse incidents. However, not all the patients we admit to the gynaecology ward for investigation of suspected OHSS have this condition and the vast majority of those who do have OHSS are moderate cases who require supportive intravenous fluids only, with no active intervention. The inspection team advised that all cases of OHSS who are admitted to the ward should be notified to the HFEA as adverse events, even though they do not necessarily meet the normal accepted definition for having severe OHSS (with ovaries >12cm diameter, clinical ascites and possible hydrothorax, electrolyte disturbance, hypoproteinaemia and evidence of impaired renal function). Whilst I do not believe the severity of their condition would justify this being reported as an adverse event, we are happy to comply with this request. It would be helpful to have a clear definition of what the HFEA consider to be 'severe OHSS' to allow comparable reporting by all licensed centres. I would not want over-reporting of what are 'moderate OHSS' cases by our unit to give an inaccurate impression of the incidence of OHSS in our unit.

We do manage cases of OHSS in patients from our area who have attended other clinics in the UK and abroad. I presume that we would not be expected to notify these patients to the HFEA as adverse incidents.

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

Regarding the inspection teams' comments about the delay in payment of licence /treatment fees (Page 9 of the report), our Nominal Licensee has already had discussions with the HFEA and the North Bristol Trust Finance Department about the best time for invoices to be sent, to meet the normal monthly payment dates used by the Trust. I hope this will reduce the delay in payments being made.

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

HFEA Executive Licensing Panel Meeting
14th October 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 2

Bristol Centre for Reproduction Medicine (0295), 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 Secretary: 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 (28 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 21st January 2009.
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 9th September 2009
- Indicative sanctions guidance approved by the Authority on 18th March 2009
- Licence application and any relevant documentation

1. The Panel noted that the centre has recently been formed by an amalgamation of the Southmead Fertility Service and The Centre of Reproductive Medicine, University of Bristol. The centre has been licensed by the HFEA since 2008.

2. The Panel considered the papers which included the report of the Interim inspection including the response of the Person Responsible (PR), and previous committee minutes.

3. The Panel noted that the inspection found the following areas for Improvement:

   - Payment of HFEA invoices within required timeframe
   - Reporting cases of severe OHSS as adverse incidents

4. The Panel noted the PR response and that there is some clarification needed between the inspectorate and the PR in relation to the reporting of OHSS, and acknowledge that there needs to be more work carried out by the HFEA in order to clarify the definition of 'severe OHSS'.

5. The Panel were satisfied from the response of the PR that the recommendations would be addressed.

The Panel's Decision

6. The Panel decided to continue the licence at this time with no additional conditions.

Signed..... Date 22 October 2009
Peter Thompson (Chair)