Renewal Inspection Report

Oxford Fertility Unit
0035

Date of Inspection: 25th June 2008
Date of Licence Committee: 11th September 2008

Centre Details

Person Responsible	Mr Joseph Enda McVeigh
Nominal Licensee	Mr Tim Child
Centre name	Oxford Fertility Unit
Centre number	0035
Centre address	Level 4, Women's Centre John Radcliffe Hospital Headington Oxford OX3 9DU
Type of inspection	Renewal
Inspector(s)	Dr Andy Leonard (Lead) Mrs Ellie Suthers Ms Sarah Hopper
Fee paid	Yes
Licence expiry date	L0035/11/a; 31/12/2008
NHS/ Private/ Both	Private Clinic; NHS and private patients

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About the Inspection:

This inspection visit was carried out on 25th June 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between 26th June 2007 and the 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

The Oxford Fertility Unit was first established as a HFEA licensed clinic in 1992. This private clinic is located in the John Radcliffe Hospital, Oxford, and provides licensed treatment for self-funded and NHS patients. The Centre is open 7 days a week, 08.00 to 16.30 Monday to Friday and 08.00 to 12.00 on Saturday and Sunday. Egg collections, IUI and DI are performed Monday to Friday, while embryo transfers are performed 7 days a week. The Centre has two satellite clinics, one at the Great Western Hospital, Swindon, the other at the Berkshire Independent Hospital, Reading. A member of medical staff is contactable 24 hours a day, 7 days a week via an emergency number provided in patient information and also by the Centre answerphone.

The unit has a robust Quality Management System (QMS) in place, an experienced quality manager in post and has been ISO9001:2000 certified since 2004. There is an annual re-certification assessment.

The PR is dual accredited with the General Medical Council (GMC) as both Consultant Obstetrician & Gynaecologist and sub-specialist in reproductive medicine. He is also the designated consultant for the Centre.

In May 2007, the Centre's application to vary their licence for the EU Tissue and Cells Directive requirements was upheld. The Centre was interim inspected in June 2007; minor improvements only were required in all areas and the recommendation to continue the licence was approved. The Centre's licence is due to expire on 31st December 2008 and includes:

- **Storage of Embryos**
- **Storage of Sperm**
- **Storage of Eggs**
- **In Vitro Fertilisation (IVF)**
- **Treatment with Donor Gametes and Donor Embryos**
- **Procurement and Distribution of Gametes and Embryos**
- **Processing of Gametes and Embryos**
- **Insemination**
- **Intra Cytoplasmic Sperm Injection (ICSI)**

There have been no significant changes in the Centre in terms of activity, patient demographics or premises since the last inspection, except the introduction of the satellite clinical service at the Berkshire Independent Hospital, Reading.

Centre activities[1] for the time period 1st March 2007 to 28th February 2008

In vitro fertilisation (IVF)	572 cycles
Intracytoplasmic sperm injection (ICSI)	338 cycles
Frozen embryo transfer (FET)	338 cycles
Donor insemination (DI)	145 cycles
Gamete intrafallopian transfer (GIFT)	NO
Research	YES (R0111; R0143; R0149)
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.

Summary for Licence Committee

Some improvements are required but the Inspectorate are satisfied with the key areas of service provided by the Centre and recommend renewal of the Centre's licence without 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 Quality Manager described problems with maintaining annual document review in the clinical embryology laboratory. Some documents are not reviewed within the 12 month time frame required by Code of Practice, 7th edition, Standard S.5.2.5. The inspectorate also noted that some procedures, e.g. Laboratory 1.11 embryo audit, have more than one year between the 'reviewed date' and the 'valid until' date in the document control footer. The PR is reminded of the need for annual review of documents comprising the quality management system, as per Standard S.5.2.5	The PR should ensure annual review of documents within the quality management system.	30th September 2008. To be monitored on next inspection

It was noted that the Centre main door and clinical corridor door were unlocked during the day, and it was explained by Centre staff that this was for fire safety reasons. Rooms within the Centre had key-pad lockable doors and these rooms were occasionally not closed during the day, even though no staff were present within them and the doors were not easily visible to staff in the Centre. This could be considered a security risk as the public had open access to the Centre through the main Centre door and clinical corridor door. While licensed material did not appear to be at risk on the day of inspection, patient records in the administration offices, staff and Centre property, and staff safety, may have been at risk. This is a potential breach of Code of Practice, 7th edition, Standard S.6.3.1 ('The Centre shall have Documented Procedures for controlled access') and S.6.3.2 ('The Centre shall provide a safe working environment for all staff.').	The inspectorate recommend that the PR risk assess security within the Centre given the current practices and implement control measures if risk assessment indicates them to be necessary.	31st August 2008. To be monitored on next inspection
Review of 10 patient records indicated 3 sets of records had problems with regard to Welfare of the Child (WoC) assessment. In one set, no consent to disclosure or WoC form was present, and in the other 2 sets, a doctor had failed to sign the WoC form. It is accepted that the WoC form may have been mislaid from the first set of notes. The Centre must ensure that WoC assessments and consents to disclosure are completed as stated in their procedure for this process and required by Licence Condition A.12.4 and Code of Practice, 7th edition, S.7.2.1.	The Centre must ensure that WoC assessments and consents to disclosure are completed as stated in their procedure	Immediate action required; to be monitored against on next inspection
The scientific inspector noted that ICSI needle and freeze straw traceability data is not retained. The Centre must ensure that logs of equipment, environmental monitoring and of products coming into contact with embryos or gametes are maintained and stored for the relevant	Appropriate records must be maintained	31st August 2008. To be monitored on next inspection

time periods, as outlined in standard licence conditions A.3.2 and A.10.30.		
New laboratory procedures and equipment are validated but long-standing procedures are not. This is a breach of standard licence condition A.11.11 and Code of Practice, 7th edition, Standards S.7.8.3. The Clinical Laboratory Director is aware of the need for validation and it will be undertaken when professional body guidelines are published.	It is recognised that an Association of Clinical Embryology validation programme with guidelines, in association with the HFEA, is in development. It is recommended that the Centre identifies critical processing procedures and prepares a prioritised plan for their validation	Action on release of ACE guidelines. Progress to be monitored at the time of the next inspection.
The Centre has an oestradiol assay machine on site and this is used for patient monitoring. At the last inspection it was recommended that this service was accredited by an appropriate organisation. The PR said in the pre-inspection questionnaire that 'accreditation of the assay laboratory is not complete as a potential move to new premises may mean outsourcing oestradiol samples.' The Code of Practice, 7th edition, Standard S.7.8.2, states that if the Centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation. It is noted at S.7.8.2 that the pathology disciplines involved in diagnosis and investigation include clinical biochemistry	The PR should review the requirement for accreditation of the oestradiol assay laboratory. If it is concluded that the laboratory should obtain accreditation then the PR should be able to demonstrate significant progress towards obtaining accreditation at the time of the next inspection.	To be monitored at the time of the next inspection.
Application of the audit tool for assessing transportation processes indicates that the Centre's SOP for transporting samples to other centres should be revised to ensure compliance with the Code of Practice, 7th edition, S.7.7 to include: 1) That the authorised person is satisfied that the transport vessel does not contain other samples	Centre's SOP for transporting samples to other centres should be revised to ensure compliance with the Code of Practice, 7th edition, S.7.7.	30th September 2008. To be monitored on next inspection

and is suitably primed and prepared. 2) A procedure to apply in cases when patient markings on samples have degraded. 3) All information which must be included in the labelling on the exterior of the package 4) That the authorised person releasing the samples to a Third Party has been appropriately trained in the process. 5) The processes required to prepare the transport vessel. 6) Verification that the equipment is suitable for transportation 7) That the authorised person preparing the equipment, samples and paperwork for shipping has been appropriately trained in the process		

Non-Compliance

Area for improvement	Action required	Time scale
Three errors of recording witnessing signatures were noted in 5 sets of patient records. It was also noted that patient samples are labelled with the patient's initial and surname and if a dish, the date on which it was prepared, but not with a unique identifier. Thus witnessing can not be compliant with non-compliant with Code of Practice, 7th edition, Guidance G.13.1.2, which requires the use of a unique identifier. Witnessing during egg collection also raised a minor concern. The patients name is written on the treatment room white board and the dish into which an egg is placed is identified by the embryologist, verbally calling out the name upon the dish to the nurse before placing an oocyte in it. The nurse then calls back the patient name to the embryologist to confirm that it tallies with the name on the white board. The identification on the dish is not directly witnessed by another embryologist or the	It is recommended that the Centre review witnessing procedures to attain compliance with all witnessing guidelines, as detailed in the Code of Practice, 7th edition. If the Centre chose not to follow this guidance, the justification for each non-compliance should be documented. It is also recommended that the Centre introduce active audit of witnessing in patient records, to confirm it is being performed and recorded appropriately.	30th September 2008. To be monitored on next inspection

nurse, which is potentially non-compliant with Code of Practice, 7th edition, S.7.8.15 'Centres shall have 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 process. These checks shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.' The Laboratory Manager recognises the witnessing method is 'slightly unconventional' and has completed a risk assessment and provided a recent audit of the oocyte collection procedure, including witnessing, to the inspectorate. The Laboratory Manager considers this method of witnessing minimises the risk of involuntary automaticity inherent in using a second embryologist to witness the collection of each oocyte in this procedure.		

Recommendations

Area for improvement	Action required
A single person is responsible for all data entry at the Centre on the HFEA electronic data interface. The workload is significant as Centre activity is considerable and manual EDI data entry is required, because the Centre's patient database does not interface with the EDI system due to form changes. This has led to a substantial number of errors in the Centre's EDI entries for 2008. These have yet to be addressed as, in the lead up to the inspection, the person responsible for EDI entry had to concentrate on removing errors from the 2007 dataset prior to the deadline for its release on the HFEA website. This person says that errors in the 2008 EDI data will be rectified as soon as possible, but this will take approximately 2 months.	It is recommended that the Centre consider training other administrative staff in this area to spread the workload and to allow a more rapid resolution of the issue.
Neither the SOPs for sperm and embryo storage audit, nor the audit reports provided from December 2007, discuss the requirement to audit stored samples and storage logs against the patient records. It is recommended that the Centre include a review of the	It is recommended the Centre consider including a review of patient consents for storage in patient records during the dewar audit, and including this

consents in patient records against the stored material and storage logs in the audit SOP and audit results. This will assist in preventing a breach of Code of Practice, 7th edition, Standards S.7.8.11: 'The laboratory's Documented Procedures shall also be established to ensure that gametes and embryos are not stored beyond the maximum period as laid down in statute, or the storage period consented to by the Patient(s) if less than the former.'	step in the dewar audit SOP.

Changes/ improvements since last inspection

Recommendations	Action Taken
It is recommended that a risk assessment be undertaken into the lack of alarms in the semen production rooms. .	Risk assessment has been carried out in the sperm production rooms
It is recommended that the oestradiol assay process be accredited by an appropriate authority.	Accreditation of Assay lab is not complete as potential move to new premises may mean outsourcing oestradiol samples.
It is recommended that an older laminar-flow workstation within the laboratory be assessed for its continued use due to its poor air-quality	Laminar flow hood has been replaced
The unit should ensure that witnessing of day-1 fertilisation checks comply with CH(04)02	Instigated contemporaneous witnessing of all procedures within laboratory.

Additional licence conditions and actions taken by Centre since last inspection

Information regarding counselling service has been included in the information sheets patients receive later in the treatment cycle; i.e information following embryo transfer.

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
The Centre quality manual contains an organisational chart with clear lines of responsibility which appear to reflect the situation 'on the ground'. The PR is in ultimate control of the Centre but delegates authority to his departmental managers. Medical issues are delegated to the Medical Manager (a senior fertility consultant), scientific matters to the Clinical Laboratory Director, nursing matters to the Nurse Manager (a fertility nurse), administrative matters to the Administration and Finance Manager and quality management system issues to the Quality Manager. The PR is dual accredited with the General Medical Council (GMC) as both Consultant Obstetrician & Gynaecologist and sub-specialist in reproductive medicine. He is also the designated consultant for the Centre. The Centre Management team have responsibility for resource management in their areas and these are integrated to provide centre-wide resource management at weekly management group meetings, the minutes of which were evidenced by the inspectorate. The PR is the accredited consultant and clinical standard operating procedures (SOPs) are reviewed annually by the PR and/or Medical Manager, and updated after discussion between the two. The Centre utilises the local trust Clinical Governance Policy. Adverse clinical outcomes are reported to the local trust and the HFEA if appropriate. Hospitalised cases of ovarian hyperstimulation syndrome are all reviewed by the Medical Manager to assess whether the stimulation protocol and treatment was appropriate, and for other learning points. The Centre is a compliant reporter of serious adverse events, the Clinical Laboratory Director, being the incident reporting officer. An appropriate incidents log was provided which detailed investigation and actions to improve procedures to minimise the risk of recurrence. Adverse events at the Centre in the last year have been dealt with in a professional manner. Discussions with centre staff indicate an open and positive 'learning' attitude regarding incident reporting and investigation.

The Centre's complaints procedure was on display in the patient waiting room. The Centre has a nominated Complaints Officer who attends the Centre daily but is only full-time on Friday. Complaints are all logged, even if made verbally, as is their review and any follow up actions. This complaints log was evidenced. Complaints are dealt with by the Centre but an annual report with complaints anonymised, is made to the local NHS Trust risk management system. The Centre has resolved all complaints it has received in the last year.

The Centre is compliant in risk management and each room on the licensed premises has been risk assessed. Process/activity risk assessment is also performed in the Embryology Laboratories and clinical areas.

The Centre has a formalised contingency plan with the fertility unit at The Hammersmith Hospital for emergency service provision in the event of significant failure(s) in the Centre.

The PR stated that all third party agreements are in place and are subjected to annual review. This is currently in process so some third party agreements past their annual review period as the new versions have yet to be returned by the third parties. These are being followed-up by the Centre. A file of third party agreements was evidenced.

Integrated control of the Centre is achieved through weekly management group meetings, the minutes of which were observed on inspection and are available to all staff. Centre activity levels are discussed at these meetings to ensure activity levels are safe given the resources available. Monthly departmental team meetings are also held, as are monthly all staff unit meetings. Research and clinical seminars are a component of most unit meetings, which allows researchers on the three research projects to feed findings back to other staff and raise awareness of the projects. 'Staff suggestions' constitutes a permanent item on unit meeting agendas. Minutes are taken at all departmental and all staff meetings, and are available to all staff the Centre's computer server. Minutes from management and departmental meetings were provided to the inspectorate. They were considered to be well presented and highly detailed, providing clear descriptions of subjects discussed and actions required.

HFEA Alerts are disseminated from the PR to management and staff by email, if urgent, and/or to management at the regular management groups meeting. Managers cascade HFEA Alerts to staff by email or at the monthly departmental meetings. Alerts are also discussed, if appropriate, at monthly all staff meetings.

This Centre had on the 20th June 2008 no invoices outstanding. The Centre takes on average 37 days to pay invoices according to HFEA Finance Department. The lack of any current outstanding invoices beyond the 28 day payment period indicates the Centre are currently compliant with Licence Condition A.13.3

Areas for improvement
None

Areas for consideration
The PR said that he has completed the PR entry programme in June 2007. No record of this is however present in the Centre files at HFEA.

There is an anticipated change to new premises by early 2009, these being in a renovated and refurbished building on the edge of Oxford. Drawings of the planned Centre were provided and funding is in place
Executive recommendations for Licence Committee
None
Evaluation
No improvements required
Areas not covered on this inspection
All areas covered

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]
In the last year (March 2007 – February 2008), the Centre reported 1248 IVF and ICSI treatment cycles whereas in the previous year 1246 cycles were performed The live birth rate for all IVF/ICSI treatment cycles in March 2006 – February 2007 was 25% which was not significantly different from the national average for all centres during this time. Considering data recorded between April 2004 and March 2007, when age stratified (<35 years; 35-37 years; 38-39 years; 40-42 years and >42 years), IVF/ICSI, frozen embryo transfer and donor insemination live birth rates in all age groups were not significantly different from national averages, except for frozen embryo transfers in <35 years and 38-39 years, in which live birth rates were significantly greater than the national average.
Areas of firm compliance
The Centre is ISO 9001:2000 certified and has a well developed quality management system. The Quality Manager is also a nursing sister; she splits her time 50/50 between these roles. The Centre are trying to recruit a secretary to assist the Quality Manager but have yet to find an appropriate recruit. There is a nominated Deputy Quality Manager who is an embryologist whose main role is to provide monthly reports of key performance indicator (KPI) monitoring. The departmental heads are the designated quality representatives in their respective areas. Regular Quality Management meetings are held and detailed minutes of these were evidenced. A quality policy signed by the PR was evidenced in the patient waiting area which defines the Centre's quality objectives and commitment to its patients. The Centre has a well developed quality manual with an extensive index. The quality manual is available on the Centre server with one complete hard copy being retained. Further copies of SOPs can be printed but are marked as uncontrolled. The managers of each department are responsible for quality manual documents in their areas. The Quality Manager has a spreadsheet index of all documents with review dates, version numbers and authors. This is regularly reviewed so the Quality Manager can advise departmental managers that documents require review. Reviews are performed and are released to the quality manual through one of three authorisers. New/revised SOPs are notified to staff at departmental meetings. Documents have appropriate document control footers.

Quality management review and evaluation was appropriate. Quality objectives and KPIs (e.g. referral rates; cycle numbers; cycles when <4 eggs collected; fertilisation rates; uncleaved embryo rates; pregnancy rates) are defined in the quality policy and manual. Quality targets are set annually at the quality management meeting held each January, then performance against them is reviewed at an interim meeting in July and a final meeting the following January. Last year, Centre 0035 achieved its targets of improving pregnancy rates, patient satisfaction and outstanding fee payment, and implementing day 3 embryo transfers. Once a month, the weekly Management Group meeting focuses on quality management issues and the monthly KPI monitoring report produced by the Deputy Quality Manager.

The Centre has an active programme of audit and reported in 2007 carrying out 32 internal audits and having had 5 external audits of aspects of their service. Detailed audits with summaries and action points were observed on the Centre computer server. Audit results were seen to be discussed in the quality management review minutes for January 2008. SOPs in the clinical and medical areas are reviewed annually against professional body guidance and compared with those from other fertility units, e.g. the Lister Fertility Clinic and the Hammersmith Hospital, to ensure they reflect best practice.

Feedback from patients is obtained through focussed patient satisfaction surveys regarding aspects of the service which have been modified, carried out approximately twice per year. Patient complaints and comments are also reviewed at management group meetings. Patient satisfaction surveys with action points for improvement were evidenced by the inspectorate. The Centre complaints policy and procedure is displayed in the patient waiting room. The Centre has a nominated Complaints Officer and complaints, their review and follow up actions are logged; the Centre complaints log was evidenced. The Centre has resolved all complaints it has received in the last year.

Areas for improvement

The Quality Manager described problems with maintaining annual document review in the clinical embryology laboratory. She said that due to activity directly related to patient treatment, some documents are not reviewed within the 12 month time frame required by Code of Practice, 7th edition, Standard S.5.2.5, as staff do not have enough time. The Centre log when such documents are out of date, and when reviewed and released, ensure the future review date reflects the 'old' review schedule, rather than the new. The inspectorate also noted that some procedures, e.g. Laboratory 1.11 embryo audit, have more than one year between the 'reviewed date' and the 'valid until' date in the document control footer. The PR is reminded of the statutory need for annual review of documents comprising the quality management system, as per Standard S.5.2.5.

Areas for consideration

None

Executive recommendations for Licence Committee

Licence Committee is asked to endorse the recommendation made in relation to the area for improvement cited above.

Areas not covered on this inspection

All areas covered

Evaluation
One improvement is required.

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
The inspectorate considered that the premises were in appropriate for the Centre's activities. On entry from the main hospital lift area to the Centre through lockable doors (open during service hours), one passes along a corridor with staff offices, a locked patient records store and consultation rooms. The corridor opens into a large patient waiting area with a reception desk. This waiting area contains seating for approximately 15 patients, access to toilets, a drinks machine and a children's play area. The centre licence, quality policy and complaint's procedure were on display, as well as a range of patient information related to fertility treatment, counselling and contact details for patient support groups. The Centre administration offices and telephone/appointment booking desk are in rooms behind the reception desk. The reception desk contains drawers with patient information regarding treatment, which is provided by receptionists and nursing staff on request or during consultations. This information showed evidence of document control. The finance office is also adjacent to the waiting area. To the right of the patient waiting area, a corridor leads to 3 scanning rooms, a nurses room, a 3 bed recovery area, 2 staff changing rooms, a sluice/rubbish storage room, two treatment rooms with the clinical embryology laboratory complex between them, managers' offices, a dewar store and two male production rooms. The corridor then exits the Centre through lockable doors (open during service hours), back to the main hospital lift area. The premises are inspected for health and safety purposes and each room has been risk assessed in the last year. The Centre premises are cleaned by the contractor who provides this service to the John Radcliffe Hospital. The Centre are concerned with the quality of this service and have asked the trust to audit the cleaning service provided, though the premises appeared clean and tidy on the day of inspection. Clinical areas were clean and appeared comfortable and appropriately equipped. Bays in the recovery area were fitted with oxygen and suction lines, and emergency call buttons, and oxygen and suction lines were available in the two treatment rooms. An emergency resuscitation trolley was present in the recover area, which was seen to have been signed off for daily checks of contents and cleanliness. The scanning and consulting rooms were also comfortable and clean, and the scanners were within service periods.

The laboratory premises were also considered compliant. They are regularly cleaned and a sign off sheet for this was evidenced. Laboratory equipment showed evidence of annual servicing and laboratory incubators and other key equipment were connected to a power supply which is backed up by the hospital's emergency generator, which is tested monthly.

A counselling room is available adjacent to the Centre within the hospital. This room is private, quiet and comfortably furnished. The psychologist who provides the counselling service says a larger room would be advantageous and looks forward to improved facilities when the Centre relocates. The room was considered by the inspectorate to be fit for purpose.

Air quality in the laboratory is compliant with the requirements of the Code of Practice, 7th edition. No specific clean air system has been installed in the clinical laboratories and air is provided through standard air conditioning units. An SOP is in place for air quality monitoring which was seen on inspection. It describes that air quality is monitored on a monthly basis by the Pharmacy Department at Stoke Mandeville hospital, using swab, contact plates and a biotest airborne contamination test device. A report on background and working environment air quality is then provided to the Centre with the results in tabulated form; a test report was provided to the inspection team. The Clinical Laboratory Director stated that the testing team use calibrated equipment for monitoring air quality. A summary of results provided to the inspectorate indicated that the background air quality is at grade C or D. Working environment air quality is generally at grade C albeit quality did drop in one air flow cabinet. Tthe monitoring log shows that this was noted and a new hood purchased in response.

All equipment at the Centre is covered on contracts to ensure annual servicing and maintenance and equipment sampled was within servicing intervals. Evidence of equipment monitoring was also seen for laboratory equipment, e.g. incubators, hot blocks and fridges.

The cryostore has a key pad locked door to which only certain centre staff have the access code. The cryostore is equipped with a low oxygen alarm and the cryostore door labelled with appropriate hazard signage and the procedure for responding to the low oxygen alarm. It contains 8 dewars, separate dewars being used for quarantined and non-quarantined samples. The dewars are equipped with low nitrogen alarms connected to a central monitoring and dial out facility. The storage facilities for embryos and gametes were considered compliant except for the issue raised below in areas for consideration.

Staff are provided with facilities in a changing room/toilet suite and a common room. The former was considered small but the staff facilities were compliant with the requirements of the Code of Practice, 7th edition.

Records of patients undergoing treatment are kept in the nurses' office for review, or in the administration offices behind the reception desk for typing of letters and scheduling of further appointments. When records are in use in the clinic, tracking slips are used to prevent them being mislaid. Patient records are stored within the Centre records store if patients have undergone treatment in the previous three years. This store is fitted with a key-pad locked door with no markings to identify the room from the exterior. The access code is known only to Centre staff according to the Medical Manager. Inactive records are stored off-site at a specialist data repository, in sealed boxes labelled with a code rather than patient identifying information. Counselling records are stored in two locked filing cabinets in the counselling room, which is itself kept locked when not in use.

Areas for improvement
It was noted that the Centre main door and clinical corridor door were unlocked during the day, and it was explained by Centre staff that this was for fire safety reasons. Rooms within the Centre had key-pad lockable doors and these rooms were sometimes not kept closed during the day, even though no staff were present within them and the doors were not easily visible to staff in the Centre. This could be considered a security risk as the public had open access to the Centre through the main Centre door and clinical corridor door. While licensed material did not appear to be at risk on the day of inspection, patient records in the administration offices, staff and Centre property, and staff safety, may have been at risk. This is a potential breach of Code of Practice, 7th edition, Standard S.6.3.1 ('The Centre shall have Documented Procedures for controlled access') and S.6.3.2 ('The Centre shall provide a safe working environment for all staff.'). The inspectorate recommend that the PR risk assess security within the Centre given the current practices and implement control measures if risk assessment indicates them to be necessary.
Areas for consideration
It was noted that two dewars used for sperm samples were stored in the clinical area adjacent to the laboratory. These dewars are equipped with low nitrogen alarms connected to the monitoring facility, however the clinical area is not fitted with a low oxygen monitor. This situation has been risk assessed by the PR. It has been assessed to be a minimal risk as the air circulation rate and room volume are large enough to prevent a nitrogen spillage from lowering oxygen in the room to a dangerous concentration.
Executive recommendations for Licence Committee
Licence Committee is asked to endorse the recommendation made in relation to the area for improvement cited above.
Areas not covered on this inspection
All areas covered
Evaluation
One improvement is required.

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
After referral and an initial consultation for those patients who have not attended the fertility/andrology clinics at the John Radcliffe Hospital, all patients must attend an open evening at the Centre. These are held fortnightly, and allow patients to experience the Centre and learn about fertility treatment, counselling, consenting and research projects, through presentations by clinical and nursing staff. Patients are also provided with written information on these subjects to take away and consider. This information was provided to the inspectorate and it was consider well written and presented, and fit for purpose. The Centre has a procedure, provided to the inspectorate, to ensure that all information is provided to patients and that they have an opportunity to ask questions, prior to consent forms being signed. The patient pathway subsequent to the open evening also includes several consultations at which information is imparted and consent forms are signed, before licensed treatment starts. These control measures ensure patients are well informed regarding their treatment and that informed patient consent is obtained. Review of 10 patient records indicated that all HFEA consent forms had been completed appropriately The Centre has a Welfare of the Child procedure in place which ensures that the assessment is completed and reviewed and that consent for disclosure is taken. Nursing staff with any concerns in this area report them to the Medical Manager who reviews the situation with clinical staff if needed. If still concerned he can obtain a report from the patients General Practitioner and/or ask the psychologist who provides the counselling service to provide an assessment. If the case is considered difficult, the Centre can access specialist services through the local hospital trust. The Centre also have access to an ethics committee. Access to patient records is well controlled and a specified person is responsible for managing patient records. Patients can obtain a copy of their patient records by written application to the Centre, signed by both patients. One member of the administration team has responsibility for photocopying the notes and sending them to the patients. Patient records are subjected to a HFEA compliant records control policy which describes the appropriate 10, 30 and 50 year document retention periods.
Areas for improvement
Review of 10 patient records indicated 3 sets of records had problems with regard to Welfare of the Child (WoC) assessment. In one set, no consent to disclosure or WoC form was present, and in the other 2 sets, a doctor had failed to sign the WoC form. It is probable that the WoC form had been mislaid from the first set of notes. The Centre must ensure that WoC assessments and consents to disclosure are completed as stated in their procedure for this

process and required by Licence Condition A.12.4 and Code of Practice, 7th edition, S.7.2.1.
Areas for consideration
A single person is responsible for all data entry at the Centre on the HFEA electronic data interface. The workload is significant as centre activity is considerable and manual EDI data entry is required, because the Centre's patient database does not interface with the EDI system due to form changes. This has led to a substantial number of errors in the Centre's EDI entries for 2008. These have yet to be addressed as, in the lead up to the inspection, the person responsible for EDI entry had to concentrate on removing errors from the 2007 dataset prior to the deadline for its release on the HFEA website. This person says that errors in the 2008 EDI data will be rectified as soon as possible, but this will take approximately 2 months. It is recommended that the Centre consider training other administrative staff in this area to spread the workload and to allow a more rapid resolution of the issue.
Executive recommendations for Licence Committee
Licence Committee is asked to endorse the recommendation made in relation to the area for improvement cited above.
Areas not covered on this inspection
All areas covered
Evaluation
One improvement is required.

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
NMC registered nurses	9.2
Non NMC registered clinical staff	1
HPC registered scientists	6.4
Scientists working towards registration	1
Laboratory support staff	1.6
Support staff (receptionists, record managers, quality and risk managers etc)	10.6
Counsellors	0.4

Summary of laboratory audit
The Centre provided audits of stored gametes and embryos from December 2007. These audits were considered robust and compliant by the inspectorate, with the exception of the issue raised in areas for improvement When audited, 5339 embryos were present as expected. In three cases, there had been a loss of computer or paper records, which was made good by copying from the record in the other medium. The audit also records 31 minor incidents of paper or computer records not being precisely accurate. These were again corrected easily. Finally the audit recorded that 376 embryo thaws and 363 freezes were performed in 2007. Regarding the sperm audit, the Centre had transferred sperm samples from three tanks and written new storage logs for these samples. 976 sperm samples were observed in storage, as expected. 21 errors were found in which a straw had been used but this was not recorded on the computer database, only in the paper log and patient record. 9 errors due to mis-filing of paper records were noted. 7 data conflicts between the computer database and the paper log occurred, these being resolved by reference to the patient records. In 5 cases, straws were not recorded in either the paper log or the computer database, these being resolved by

reference to the patient notes and the record in the other media. Finally, in 5 cases straw location was incorrectly recorded on the paper log, this being corrected by searching the dewars after referencing the computer database, finding the straws, and recording their correct stored locations in the paper record. Finally the sperm audit recorded that 96 thaws, 42 discards and 218 freezes have been accomplished in 2007.

Summary of spot check of stored material

A limited spot check of one sperm and one embryo sample was performed with no errors in paperwork or sample position being found

Areas of firm compliance

The Centre has an established induction programme in which all new staff and those returning to work after career breaks, undertake a training programme in the Centre's activities, as well as the standard local trust induction programme (which covers basic life support, health and safety, fire safety and manual handling). Induction training in the Centre involves six months of active mentoring and signing off of competencies to complete required procedures. Logs of induction training were evidenced for staff in several different roles.

The Centre has robust systems of competency assessment for all staff. The competency of ultrasound scanners is checked annually by the Head of Radiology at the John Radcliffe Hospital, and nursing staff are subjected to a rolling competency assessment programme, the signing off of which was evidenced in nursing staff training records. Embryology and medical staff competency is monitored by comparison of KPIs between staff and by observation of practice in five key areas, which can be changed on a 2 year rota. There are defined KPI limits outside of which investigation of competency is undertaken and re-training initiated if needed. Staff members achieving consistently high KPI scores are used as trainers for lower scoring staff, via either 'best practice' seminars or one-to-one supervision. Adherence to SOPs is also audited in the laboratory and in clinical practice as part of competency assessment.

All staff interviewed considered that on-going training and continual professional development (CPD) needs were well supported by the Centre. For nursing and medical staff there is a wide range of courses available for CPD purposes, including mandatory basic life support training, and several staff attended conferences last year. Embryology staff also can attend conferences and take part in the Association of Clinical Embryologists (ACE) CPD programme. Junior embryologists follow the ACE training programme to gain ACE accreditation. Some embryologists have been through formal auditor training to facilitate regular audit of centre processes. The Clinical Laboratory Director and Nursing Manager both considered the training budgets they administer to be reasonable, providing staff with good access to training and CPD.

A member of medical staff is contactable 24 hours a day, 7 days a week via an emergency number provided in patient information and also by the Centre answerphone.

Donor screening was reviewed for two donors and was seen to be compliant with professional guidelines. All donors and recipients are referred to the psychologist for donor counselling. The Centre has a procedure is in place to ensure that the 10 families limit is not breached.

The Centre introduced day 3 rather than day 2 embryo transfers late in 2006 and have seen a

decline in the multiple births from 27% to 19% between 2006 and 2007. To assist with the implementation of single embryo transfer policy, the Centre are planning to introduce day 5 embryo transfers and blastocyst vitrification, and this will be discussed on a quality management away day in the near future. The 3 embryo transfer rate in 2007 was 8.15% (30 cases) in frozen embryo transfer cases and 3.26% (28 cases) in IVF-ICSI.

Patients attending the Centre for the first time are asked to bring a photograph and a passport or driving licence as proof of identity. These are photocopied and kept in patient records to facilitate later identification of patients.

The Centre has had several gamete and embryo imports and exports by HFEA Special Direction in the last year; these have been applied for and acted on appropriately.

The Centre only uses CE marked or sperm motility tested consumables and has established traceability procedures. For traceability purposes, batch records are maintained for plasticware, detailing the batch number, and the dates received and first used. Culture media, catheter details and the incubator used are logged on patient's laboratory sheets.

The Clinical Laboratory Director has provided a risk assessment of their manual witnessing procedure to the HFEA and the PR said in the pre-inspection questionnaire that 'witnessing is an integral part of a patients care. Staff are required to sign to state what they have witnessed'. The Centre clinical and embryology staff are all trained in witnessing procedures as part of the initial induction training programme and witnessing has been audited in the last year, though not competency assessed. At the weekend when limited embryology staff are on duty, a nurse is always available to enable witnessing of laboratory procedures. The inspectorate have some concerns with the witnessing procedures carried out at the Centre and these are detailed below.

The Fertility Counsellor is a chartered psychologist of 16 years experience, who provides counselling services to the unit on average 2 days per week, with occasional sessions as demand requires. The psychologist has the regular supervision required to maintain chartered status. Counselling information is provided to patients from first attendance at the unit and throughout their treatment. A dedicated secretary maintains the counselling appointment diary and patients seldom wait more than 1 week for a counselling appointment. A detailed counselling audit was submitted prior to the inspection which showed that a total of 280 clients were seen between April 2007 and April 2008. IVF, IUI and ICSI treatment accounted for 81 clients with 62% being couples, whilst 189 clients were seen concerning donation, recipient and egg-share, with 86% being couples. The majority of clients attended for 1-3 sessions and 58% were self referrals, indicating that information provided to patients regarded counselling successfully informs them of the service.

The compliance of embryo and gamete storage premises was discussed in Section 3. The Centre has comprehensive paper and electronic logs of samples in store and operates a bring-forward system. Separate dewars are used for quarantined and non-quarantined samples.

Areas for improvement

While the Centre record nearly all the equipment and consumables with which embryos and gametes come into contact which may impact on safety and quality, the scientific inspector

noted that ICSI needle and freeze straw traceability data is not retained. The Centre should review the equipment, media and consumables about which they collect traceability data to ensure that complete logs of equipment, environmental monitoring and of products coming into contact with embryos or gametes are kept, as outlined in standard licence conditions A.3.2 and A.10.30.

The Centre informed the inspectorate that all new processes and equipment introduced within the laboratory have been validated. Long-standing critical laboratory processes have however not been validated, which is a breach of standard licence condition A.11.11 and Code of Practice, 7th edition, Standards S.7.8.3. The Clinical Laboratory Director is aware of the need for validation but is waiting for the publication of professional body guidelines. It is recommended that the Centre identifies critical procedures and prepares a prioritised plan for their validation.

The Centre has an oestradiol assay machine in the andrology laboratory which is used for patient monitoring. The machine is serviced regularly and is under a maintenance contract. At the last inspection it was recommended that the oestradiol assay service be accredited by an appropriate organisation. The PR said in the pre-inspection questionnaire that 'accreditation of the assay laboratory is not complete as a potential move to new premises may mean outsourcing oestradiol samples.' The Code of Practice, 7th edition, Standard S.7.8.2, states that if the Centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patient partners or donors, or their gametes, embryos or any material removed from them, these laboratories shall obtain suitable accreditation. It is noted at S.7.8.2 that the pathology disciplines involved in diagnosis and investigation include clinical biochemistry. The PR should review the requirement for accreditation of the oestradiol assay laboratory. If it is concluded that the laboratory should obtain accreditation then the PR should be able to demonstrate significant progress towards obtaining accreditation at the time of the next inspection.

The Centre has a transportation procedure which was reviewed by the scientific inspector using an audit tool. This indicated that the procedure was compliant in many ways, but that it did not comply with some aspects of Code of Practice, 7th edition, S.7.7, specifically:

1) That the authorised person is satisfied that the transport vessel does not contain other samples and is suitably primed and prepared.
2) A procedure to apply in cases when patient markings on samples have degraded.
3) All information which must be included in the labelling on the exterior of the package
4) That the authorised person releasing the samples to a Third Party has been appropriately trained in the process.
5) The processes required to prepare the transport vessel.
6) Verification that the equipment is suitable for transportation
7) That the authorised person preparing the equipment, samples and paperwork for shipping has been appropriately trained in the process

The PR should update the transportation procedure to ensure compliance with all aspects of Code of Practice, 7th edition, Standards S.7.7.

Areas for consideration

Neither the SOPs for sperm and embryo storage audit, nor the audit reports provided from December 2007, discuss the requirement to audit stored samples and storage logs against the patient records, so that consent for storage of each sample is confirmed and tallied with

that recorded in computer and paper logs. This increases the possibility that a sample could be stored beyond its consented storage period, especially if that consented storage period has been varied from the statutory storage period. It is recommended that the Centre consider including a review of the patient records against the stored material and storage logs, in the audit SOP and audit results, to prevent breaching Code of Practice, 7th edition, Standards S.7.8.11: 'The laboratory's Documented Procedures shall also be established to ensure that gametes and embryos are not stored beyond the maximum period as laid down in statute, or the storage period consented to by the Patient(s) if less than the former.'

Three issues related to witnessing were noted:

1) The embryologists label patient samples with the patient's initial and surname and if a dish, the date on which it was prepared. In the event that two patients are in the Centre with similar names, the full patient names i.e. first name and surname are used. The lack of use of a hospital number or other unique identifier means that witnessing at the Centre is potentially non-compliant with Code of Practice, 7th edition, Guidance G.13.1.2 'Each stage of the witnessing trail should check the patient's/donor's full name and a unique identifier'.

2) When witnessing during egg collection was described to an inspector and the protocol reviewed, it was apparent that active identification of the patient was performed and witnessed appropriately. The patients name was then written on the treatment room white board. The dish into which eggs were collected was identified by the embryologist, verbally calling out the name upon it to the nurse before placing oocytes within it. The nurse then calls back the patient name to the embryologist to confirm that it tallies with the name on the white board. This witnessing is performed for each oocyte collected. The identification on the dish is not directly witnessed by another embryologist or the nurse, which is potentially non-compliant with Code of Practice, 7th edition, S.7.8.15 'Centres shall have 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 process. These checks shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.' The Centre recognise the witnessing method is 'slightly unconventional' and have completed a risk assessment and provided a recent audit of the oocyte collection procedure, including witnessing, to the inspectorate. The Laboratory Manager considers this method of witnessing minimises the risk of involuntary automaticity inherent in using a second embryologist to witness the collection of each oocyte in this procedure.

3) When witnessing compliance was checked in 5 sets of patient records, three omissions of witnessing signatures were noted, two at active verification of sperm provider identity, and one at a fertilisation check.

It is recommended that the Centre review witnessing procedures to attain compliance with witnessing guidelines, as detailed in the Code of Practice, 7th edition, Guidance G.13. If the Centre choose not to follow this guidance, the justification for each non-compliance should be documented. It is also recommended that the Centre audit witnessing in patient records, to confirm it is being performed and recorded appropriately.

Executive recommendations for Licence Committee
Licence Committee is asked to endorse the recommendations made in relation to the areas for improvement cited above.

Areas not covered on this inspection
All areas covered
Evaluation
Several improvements required.

Report compiled by:

Name Dr Andrew Leonard

Designation Scientific Inspector, HFEA

Date 4th August 2008

Appendix A: Centre staff interviewed

PR, Clinical Laboratory Manager, Administration Manager, Medical Manager, Nursing Manager, Counsellor, Junior Nurse, Junior Embryologist, Quality Manager

Appendix B: Licence history for previous 3 years

Status	Licence	Type	Active From	Expires
Active	L0035/10/a	Treatment with Storage	01/11/2005	31/12/2008
Replaced by New Version	L0035/9/d	Treatment with Storage	27/06/2005	31/12/2005
Replaced by New Version	L0035/9/c	Treatment with Storage	16/12/2004	31/12/2005
Replaced by New Version	L0035/9/b	Treatment with Storage	24/02/2004	31/12/2005
Replaced by New Version	L0035/9/a	Treatment with Storage	01/01/2003	31/12/2005

L0035/10/a
No Conditions or Recommendations on Licence

Licence Committee Meeting: 13 September 2007

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that this centre treats a mixture of NHS and self-funded patients and carries out about 1,200 cycles per year. It has been ISO accredited since 2004 and has an experienced Person Responsible. The centre's risk assessment score stands at 11%, in the low range.

2. Mr Lenton drew the Committee's attention to the finding on page 8 of the inspection report, that centre staff had not been conducting contemporaneous double witnessing when transferring fertilised eggs during fertilisation checks. The inspection team had reminded the Person Responsible that this constituted a breach of Directions D2004/4 and this had been acknowledged.

3. The Committee noted the breach and reminded the centre to comply with HFEA witnessing requirements, which are now stated at G.13 of the 7th edition of the Code of Practice.

4. Mr Lenton informed the Committee that one of the findings from a survey of patient questionnaires was that patients did not feel that the counselling service was well publicised to patients undergoing second or subsequent cycles. The Committee agreed that it would be useful for the centre to consider ways of addressing this point, particularly as patients at later

stages of treatment could be faced with different problems to patients beginning treatment.

5. Mr Lenton reviewed the recommendations made to the centre, listed on page 8 of the report, these were: that a risk assessment is carried out in relation to lack of alarms in semen production rooms, that the centre's oestradiol assay process be accredited before the next inspection and that the centre assesses the continued use of one of its laminar-flow work stations.

6. The Committee endorsed the recommendations made by the inspection team and agreed that they would expect to see them all actioned in the time suggested in the report. They agreed that the centre's licence should continue with no additional conditions.

Licence Committee Meeting: 2 May 2007
1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that the centre's risk rating, reflecting the degree of compliance with EUTD requirements, was 8%, in the low range.

2. Mr Lenton informed the Committee that this centre has already achieved ISO accreditation and will be moving to new premises at the end of this year.

3. The Committee noted that the centre is working towards full compliance with the requirements of the EUTD and that progress will be assessed at the next inspection visit to the centre.

4. The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

L0035/9/d-c
No Conditions or Recommendations on Licence

Comments from Licence Committee 12/10/05:
a) The Committee considered the recommendation by the inspection team that the centre carry out intra uterine insemination rather than intra cervical insemination for donor insemination patients. The Committee noted that the centre has agreed to review this option and agreed that they hoped that this might lead to the improvement of pregnancy rates for donor insemination patients. Members of the Committee also felt that the centre should look at the NICE guidelines on donor insemination as part of their review.
b) The Committee decided to renew the centre's licence for three years with no additional conditions. The new licence will also licence the centre for the storage of eggs.

Comments from Licence Committee 20/01/05:
a) The Committee noted the centre's low DI success rates and asked for the centre's comments on this.
b) The Committee noted the high level of errors in the audit and hoped that the centre is correct in its assertion (reported in paragraph 102 of the inspection report) that these errors have no implications for embryos in storage.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number 0035

Name of PR Mr Enda McVeigh

Date of Inspection 25th June 2008

Date of Response 19.08.08

Please state any comments regarding the inspection and actions you have taken or are planning to take following the inspection with time scales

1. Page 5: There is no mention of IVM or SSR in the list of licensed activities. *(These are not legally defined as licensed activities; Lead Inspector)*

2. The report states that we store samples for virally positive patients – this is incorrect. *(This point has been acted upon in the report by the Lead Inspector)*

3. Page 7: All laboratory SOPs ***are*** reviewed within the year. We have a document review plan for the year where **the month by which all documents must be reviewed is set**. There are over 80 laboratory SOPs so the comprehensive review of each SOP starts before this end date in order that they are all reviewed within the year. This is quite a time consuming process as they need to be first reviewed by a Senior Embryologist, then any corrections made by a member of the Quality Management team and finally signed off by the Consultant Embryologist. There is not a problem with staff shortage, but the scientists do need to fit this in around their normal clinical duties. The *valid until* date in the footer is the same date as on the document review plan. It therefore does look as if some SOPs are reviewed outside the 12 months but this is never the case as can be seen if previous years SOPs review dates are examined. We will now ensure that the valid unit date on the footer is never more than 12 months after the review date. No breach of the code has occurred as the documents were within the 12 months of their last review. *(The point regarding not being short of staff has been acted upon in the report by the Lead Inspector)*

4. Page 8: We take security in the unit very seriously. The last audit and risk assessment was done on 26/01/08 and was discussed with all members of staff at the Unit Meeting on 30/01/08.

5. Page 8: The report is correct in that we are waiting for guidelines for complete validation of laboratory processes. However we would like it noted that all **new** processes and **new** equipment which are used within the laboratory are validated *(this point has been acted upon in the report by the Lead Inspector)*. Critical equipment, such as incubators are rigorously monitored and regularly serviced. We have already prioritized the critical processes and equipment which require validation and for those where verification is appropriate this is being done. This documentation was available at the time of the inspection.

6. Page 10 & Page 28: the description of the witnessing process is only partially accurate. As you say, the nurse writes the name of the current patient on the white board. Each time an egg is

found the embryologist takes the dish from the incubator and reads out the name written on it. The nurse looks at the whiteboard to check it is the right patient and calls that name back to the embryologist to indicate that she has a. heard the embryologist and b. confirming the name of the patient is correct. It is this latter part that is missing from your report (*this element has been added in the report – Lead Inspector).* Thus double witnessing is performed and is an active rather than passive means of witnessing, which is in line with HFEA requirements. I appreciate it is slightly unconventional but we believe this is a more robust system than having a second embryologist checking the name on each dish throughout the procedure. In this situation they are likely to become bored and cease to concentrate and therefore more likely to miss an error as a result. You will be well aware that the Toft Report highlights the issues of involuntary automaticity that can arise in such circumstances. In recognition that this is a little unconventional we have recently performed an audit on the process and this was shown to your inspector on the day. I have attached a copy for your attention. You will see that witnessing was part of that audit. We initially audited this a year ago and because we felt the system was not robust then (was more passive, with the nurse just shouting yes) changed it to the current system which seems to be working well. A review of all witnessing procedures & a full risk assessment were performed by the Safety Officer in November 2007. The witnessing at oocyte recovery is done in accordance with these recommendations.

7. Page 27: The audits of sperm and embryos in storage are not checked against the notes due to the numbers involved. There are currently 1217 patients with embryos and 908 patients with sperm in storage. As each of these patients has a letter sent out annually it is more practical to check their storage consents and record of stored material against the computer records at this time. Therefore the patient records are being reviewed annually and there is no risk of breaching Standard S.7.8.11. This process is not in the SOP for Audit as it is part of the SOP for Annual Storage Letters.

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

Licence Committee Meeting

11 September 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Oxford Fertility Centre (0035)
Licence Renewal

Members of the Committee:

Clare Brown, Lay Member – Chair
Sue Price, Consultant in Clinical Genetics, Oxford Regional Genetics Service
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee
Roger Neuberg, Consultant Obstetrician and Gynaecologist, Leicester Royal Infirmary

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice:

Graham Miles, Morgan Cole Solicitors

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 (47 pages)
- no papers were tabled.

1. The papers for this item were presented by Chris O'Toole, Head of Research Regulation. Dr O'Toole informed the Committee that this private centre was first licensed by the HFEA in 1992. It provides a range of licensed treatment to both self-funded and NHS patients.

2. Dr O'Toole reported that the renewal inspection visit took place on 25 June 2008. The inspection identified a number of areas for improvement, as listed at pages 7 to 12 of the inspection report.

3. The Committee noted that the inspection identified the following areas for improvement:
   - Some documents were not being reviewed on an annual basis

- some doors at the centre were not kept locked, falling short of the requirement for controlling access
- the centre appears not to be following its procedures for Welfare of the Child assessments
- ICSI needle and freeze straw traceability data is not retained
- Long-standing procedures are not validated
- the ostradiol assay machine requires to be accredited
- the centre's procedures for transporting samples require revision
- witnessing procedures are not compliant with Code of Practice guidelines

4. Dr O'Toole drew the Committee's attention to the response to the inspection report by the Person Responsible, appended at pages 32 to 33 of the report. Dr O'Toole informed the Committee that the Person Responsible claims to have submitted his Person Responsible Entry Programme (PREP) assessment. The Executive has no record of this having been received and furthermore the PREP does not appear to have been assessed.

The Committee's Decision

5. The Committee noted the inspection report and endorsed the recommendations and timescales suggested by the inspectorate. The Committee agreed that it was satisfied that the Person Responsible has previously submitted a PREP assessment but asked that the Person Responsible resubmit it in order that it can be evaluated. This would enable the HFEA to uphold a consistent approach on this issue across all centres.

6. The Committee decided to renew the centre's licence for a period of 5 years.

Signed…… … Date……..
Clare Brown (Chair)