Interim Inspection Report

Bourn Hall Clinic
0100

Date of Inspection: 24th July 2007
Date of Licence Committee: 21st November 2007

CENTRE DETAILS

Centre Address	Bourn Hall Bourn Cambridge Cambridgeshire CB23 2TN
Telephone Number	01954 719111
Type of Inspection	Interim
Person Responsible	Dr Mike Macnamee
Nominal Licensee	Mr Peter Brinsden
Licence Number	L0100-13-a
Inspector(s)	Wil Lenton (Lead Inspector, HFEA) Andy Leonard (Inspector, HFEA) Allison Cummings (Inspector, HFEA) Gill Walsh (HFEA, Observer)
Fee Paid - date	N/A
Licence expiry date	31st March 2012

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About the Inspection:
This inspection visit was carried out on 24th July 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between June 2006 and May 2007.

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 interim 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, recommendations 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.

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

Centre 0100 was first licensed in 1991. It currently provides donor insemination, IVF, ICSI, egg sharing, IUI and freezing facilities. It is a large, active centre providing approximately 1200 treatment cycles in the last year.
The premises are based within a converted manor house and a purpose-built unit. The building is very extensive and provides an adequate, clean, private, well maintained and functional environment for patients, administrative staff, clinical and laboratory processes. Sufficient numbers of appropriately qualified and competent staff are employed at the centre. There is an organisational structure in place which defines accountability, responsibility and reporting relationships. The centre is ISO 9001 accredited.
The person responsible is appropriately qualified to discharge his duties as outlined in section 17 of the HF&E Act. It was apparent that he was familiar with clinical, nursing, laboratory, administrative and managerial aspects of the service. He is well supported by staff and an established management team.

Activities of the Centre (01/07/05 to 30/06/06)

Licensed treatment cycles	IVF 428 ICSI 450 FET 362
Donor Insemination	19
Research	Yes
Storage	Yes

Summary for Licence Committee

Centre 0100 was first licensed in 1991. It currently provides donor insemination, IVF, ICSI, egg sharing, IUI and freezing facilities. This is a large, active centre providing approximately 1200 treatment cycles in the last year.

A number of regulatory issues were identified during the course of the inspection and are summarised as follows: It is recommended that;

- the centre reviews its signing-in procedure in order to maintain patient confidentiality.
- a risk assessment be undertaken into the locking mechanism for an unsecured cryostorage dewar.
- the incident management protocol requires updating to include HFEA requirements as per CoP 7; S9.4.5
- the document control system to be applied across all centre documentation.
- patient consent documents be updated to reflect reference to the current CoP 7 where appropriate.
- the monitoring of laboratory air quality be formalised.

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

Risk Assessment

The risk assessment was calculated to be 0%, when using the risk matrix tool.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	x	

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 or Code of Practice

Breach	Action required	Time scale
A breach of confidentiality was noted at the ground floor patient reception station, where patients are asked to sign-in. Patients which undertake this process also view the names of all other patients attending on the same day.	Revision of the centres signing-in procedure in order to maintain patient confidentiality.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
Document control system to be applied across all paperwork *CoP7 - S.5.2.5/6*	Extension of the document control system to incorporate all centre documentation	6 months following LC
Monitoring of air quality to be formalised. *CoP7 – S.6.3.6/S.7.8.5*	A written protocol for the monitoring of air quality to be produced	3 months following LC
The incident management protocol was last updated in 2005 and should be reviewed to include HFEA requirements as per *CoP7 - S9.4.5*	Review/update of incident management protocol	Immediately

Recommendations	Time scale
Risk assessment of a locking mechanism for an unsecured cryostorage dewar.	Immediately
Patient consent documents need to be updated to reflect reference to the current CoP 7 where appropriate.	Immediately

Proposed licence variations

N/A

Changes/ improvements since last inspection

Recommendation	Action taken
N/A	

Additional licence conditions and actions taken by centre since last inspection

C	N/A
A	Complied Y/N

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 findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The centre was seen to be well managed by the PR, who is appropriately qualified under the requirements of the European Union Tissues and Cells Directive (EUTD), and supported by an experienced senior management team. An organisational chart was available which detailed the centre's lines of communication and reporting structure. Staff interviewed on the day felt well supported within the present management structure. The centre has been ISO-accredited since November 2005 and has a good quality management system in place, which underpins its general organisational structure. Minutes of regular meetings both at the departmental level (administration, clinical, nursing and scientific) as well as at the unit level were observed. These are available to staff via the centre's computer network. As determined from the staff list and organisational chart provided, the centre appeared to have an adequate number of qualified/trained staff to deliver the range of patient services it provides. There is a good staff training/appraisal system in place, which ensures that staff target any specific training needs, as well as attending statutory courses. Training has recently focussed on customer care aspects of the service, via analysis/discussion of patient questionnaires. Individual logs were available on the day for inspection. As part of the ongoing quality management system, an annual management review is undertaken which audit's all aspects of the centre's activities and then identifies areas for improvement in the next business plan. New staff follow an intensive induction programme which is designed to address all aspects of the centre's activities, from general topics such as confidentiality, welfare of the child, patient dignity/respect, through to more specific areas which are departmental related. This was verified via staff interviews.

Risk assessments were seen to have been carried out for all parts of the service such as ICSI equipment failure, lack of staff through to fire, explosion of gas cylinders and flooding.
There is currently a contingency arrangement in place with another licensed centre (0030) and a disaster recovery plan, which is part of the ISO system.

HFEA alerts and centre incidents are discussed at minuted departmental/unit meetings, as evidenced from interviews with staff.

Areas for improvement
The incident management protocol was seen to be from 2005 and requires updating to include HFEA requirements as per COP 7; S9.4.5
Executive recommendations for Licence Committee
Updating of incident management SOP.
Areas not covered on this inspection
None

Evaluation
Some improvements required

2. Quality of service

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

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
HFEA-held Register data (March 2002 – April 2005) indicate that; 1. IVF/ICSI/FET success rates for all age groups are higher than the national average. 2. DI success rates for women <35 are above the national average 3. DI success rates for women between 35-42 are slightly below the national average
Areas of firm compliance
As indicated from the above HFEA data success rates for all treatments are generally above the national average. Outcome data is reviewed on a regular basis and is discussed at laboratory, clinical and quality management meetings. Audits of individual practitioners were also seen during the inspection. Welfare of the Child issues can be discussed within any of the scheduled meetings (unit or departmental) if staff feel there are issues of concern. Patients notes were seen to be stored securely in a dedicated room on the first floor. Records are archived after two years inactivity. Patients interviewed on the day of the inspection identified positive areas such as the general environment of the centre, helpful, pleasant staff and adequacy of information given. All couples felt that the service provided by the centre was good. A counselling audit was supplied covering the period January 2006 to April 2007. During this time there were a total of 541 counselling sessions, broken down into; Implications counselling = 99 Support counselling = 178 Therapeutic counselling = 264

The lead counsellor is available three days per week and Saturday mornings. There is an informal arrangement with a colleague to provide cover for the service. Non-identifying patient notes are stored securely off-site. Patients are seen as soon as possible and generally within two weeks of the initial enquiry. Emergencies can be dealt with over the telephone or as soon as the patient can get to the clinic. Under exceptional circumstances a home-visit could be arranged. The lead counsellor has initiated a distance-learning course in stress management and is hoping to undertake training in Cognitive Behavioural Therapy from January 2008.

The complaints log was viewed during the inspection and found to be up-to-date with no outstanding issues.

The centre has initiated a sperm-sharing scheme, whereby male partners with good semen profiles are approached to make a number of sperm donations in return for a refund on an IVF cycle. Information concerning this scheme was viewed on the day of inspection and the general principal referred to the policy department who assured the Executive that such schemes were similar to egg-sharing schemes and are being adopted by other centres.

Areas for improvement
A breach of confidentiality was noted at the ground floor patient reception station, where patients are asked to sign-in. Patients who undertake this process can also view the names of all other patients attending on the same day.
Executive recommendations for Licence Committee
Review of patient signing-in procedure which would protect the identities of all patients.
Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs)

Evaluation
Some improvements required

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The premises/facilities are generally clean and comfortable as the centre is situated within a converted manor house, together with newer purpose-built buildings. Risk assessments have been performed and the premises/facilities found to be fit for purpose. Wheelchair access is available and all patient waiting areas were found to be clean and tidy. Secure access was observed in all patient-sensitive areas, with the laboratory area having restricted staff access. Within the laboratory all except one cryodewar were seen to be fitted with locks. The laboratory manager explained that the dewar which wasn't locked, could not be physically locked. All dewars were fitted with low-nitrogen alarms connected to an auto-dialler for out-of hours incidents. Low oxygen monitors were present within the cryostorage areas. The male semen-production rooms were seen to be clean, comfortable and fit for purpose.
Areas for improvement
Risk assessment of a locking mechanism for the unsecured cryodewar.
Executive recommendations for Licence Committee
A locking mechanism be devised for the unsecured cryodewar.
Areas not covered on this inspection
None

Evaluation
Some improvements required

4. Information

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

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Seven sets of patients records were reviewed and generally found to be appropriately completed across all treatment groups.
Areas of firm compliance
The HFEA licence, ISO accreditation, Healthcare Commission certificate, certificate of employers liability together with a Cambridge business services, 'investor in people' certificate were all prominently displayed within the patient reception area. The quality manager stated that all clinical SOPs were now updated, version-controlled, and annually reviewed, but that other paperwork relating to clinical services such as, staff list, organisational chart, still need to be brought under document control. The centre has identified an electronic document control package and will be testing the software in the near future and will strive towards a paperless system in the long term. As indicated by the PR, EDI is accessible from all pc stations. The centre has a good record of reporting treatment activities to the Authority and there are no issues reported from the HFEA Registry or Finance departments.
Areas for improvement
Document control system to be applied across all paperwork. Patient consent documents need to be updated to reflect reference to the current CoP 7 where appropriate.
Executive recommendations for Licence Committee
Document control system to be applied across all paperwork. Updating of patient consent documentation as appropriate.
Areas not covered on this inspection
None

Evaluation
Some improvements are required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	7
NMC registered nurses	13 (plus 5 auxiliaries)
HPC registered scientists	3
Scientists working towards registration	4
Support staff (receptionists, record managers, quality and risk managers etc)	9

Summary of laboratory audit
The centre conducts a rolling audit of its stored material. The scientific inspector was shown a full list of audits undertaken and assured by the senior scientist that all samples were checked annually.
Summary of spot check of stored material
Not carried out. No problems from previous renewal inspection July 2006
Areas of firm compliance
The laboratory has restricted staff access which is controlled via a swipe card system. All equipment viewed on the day of inspection had up-to-date service logs. The senior scientist indicated that a new facilities monitoring system is to be fitted in the laboratory within the next month. This will allow for the constant monitoring of critical parameters such as; i. incubator CO_2 levels ii. incubator temperatures iii. hot-plate temperatures iv. liquid nitrogen level/temperature v. air quality Laboratory outcome audits are monitored on a regular basis together with personal

performance audits which were made available on the day of the inspection.
Staff interviewed verified the induction process, which they felt was good, and stated that they were supervised within the laboratory until assessed as competent. CPD was evidenced and junior staff are encouraged to undertake certified training courses (ACE) and be aligned with professional bodies.

Witnessing and traceability within the laboratory was observed by the scientific inspector and found to be good, with three independent identifiers for each patient and each critical processing step (transfer between tube/dish) being double-witnessed contemporaneously. Culture media batch numbers were also seen to be included on the laboratory sheets.

Minuted laboratory meetings were seen to take place on a regular basis, during which alerts/incidents are discussed.

Areas for improvement
Air quality monitoring.
Executive recommendations for Licence Committee
Monitoring of air quality to be formalised.
Areas not covered on this inspection
Spot check of stored material

Evaluation
Some improvements required.

Report compiled by:

Name……Wil Lenton……

Designation… HFEA Inspector……

Date…… 24th July 2007……

Appendix A: Centre Staff interviewed

The PR and 6 staff together with 3 patients and partners.

Appendix B: Licence history for previous 3 years

2004

Licence Committee 13 December 2004
After reviewing his Curriculum Vitae, the Committee agreed to recognise Mr Tony Knox as the Person Responsible. They also agreed to recognise Mr Peter Brinsden as Nominal Licensee. Licence continued with no conditions and no recommendations.

2005

Licence Committee 31 October 2005
Licence continued with no conditions.

Licence Committee 19 December 2005
Change of PR approved.

2007

Licence Committee 2nd May 2007
Variation of current licence to incorporate the requirements of the EUTD.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……0100……

Name of P……Mike Macnamee……

Date of Inspection……24 July 2007……..

Date of Response……6 September 2007……

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

- **The centre reviews its signing-in procedure in order to maintain patient confidentiality.**
  Signing in procedure changed to maintain patient confidentiality
- **A risk assessment be undertaken into the locking mechanism for an unsecured cryostorage dewar.**
  Emergency dewar: located in area with swipe card and intruder alarm, level and temperature alarm and 24 hour security.
  Dewar 12 (screened sperm samples) locked room, located in area with swipe card and intruder alarm, level and temperature alarm and 24 hour security.
  Both have been modified to secure lids, under lock.
- **The incident management protocol requires updating to include HFEA requirements as per CoP7; S.9.4.5**
  Will be completed by end Sept 07.
- **The document control system to be applied across all centre documentation.**
  All documents are currently controlled and will be centrally controlled by Q2 2008
- **Patient consent documents be updated to reflect reference to the current CoP7 where appropriate**.
  Currently under review.
- **The monitoring of laboratory air quality be formalised.**
  To be formalised by end September 2007.

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

Signed……

Name……Mike Macnamee……

Date……6 September 2007……

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).

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

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

21 November 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 4

Bourn Hall Clinic (0100)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Trish Davies, Director of Regulation / Deputy Chief Executive
Rebekah Dundas, Lay Member	Stephanie Sullivan, Interim Head of Inspection
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Claudia Lally, Committee Secretary
	Providing Legal Advice: Sarah Ellson, Field Fisher Waterhouse

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

The following papers were considered by the Committee:

- papers for Licence Committee (30 pages)
- no papers were tabled.

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that the centre has been licensed since 1991 and provides approximately 1200 treatment cycles last year. The centre has a good history of regulatory compliance and has been ISO accredited since 2005, with a well developed quality management system.

2. Mr Lenton further informed the Committee that the interim inspection visit to this centre took place on 24 July. He discussed the inspection report with the Committee and summarised the regulatory issues listed at page 8 of the inspection report. One of these related to the fact that when patients arrive at the centre they are shown a list containing the names of all patients expected that day. Mr Lenton informed the Committee that the centre has now changed its practice for signing in patients. Mr Lenton read from the Person Responsible's response to the inspection report and confirmed that on the basis of this

response he is satisfied that the centre is in the process of addressing all of the breaches identified by the inspection team.

3. The Committee agreed that the centre's licence should continue with no additional conditions.

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